Pacific EcoRisk

Quality Manual

Pacific EcoRisk

Quality Manual

Pacific EcoRisk, Inc.
2250 Cordelia Road
Fairfield, CA 94534
(707) 207-7760

Revision 24

September 2021

Approved by:

Jeffrey S. Cotsifas, President Special Projects Director Ph: 707-207-7760	Signature	Date 9/23/21
Stephen L. Clark, Vice President Special Projects Director Ph: 707-207-7760	Signature	Date 9/23/21
Brant C. Jorgenson, Ph.D., Vice President Special Projects Director Ph: 707-207-7760	Signature	Date 9.23.21
Bella Volpatti Quality Manager Ph: 707-207-7760	Signature	Date 9/23/21
Charlene Derheim Laboratory Manager Ph: 707-207-7760	Signature	Date 9/23/21

History of Changes

Revison	Date	Description of Change
23	6/14/21	Removed references to the position of Office Manager, changed "QA Manager" title to "Quality Manager", changed "Technical Director" title to "Technical Manager, and other minor editorial changes.
24	9/23/21	Updated section 3.2.2 to comply with 22 CCR §64802.05(b)(1)(A) and document the annual review of each test method SOP.

Quality Policy Statement

Pacific EcoRisk (PER) maintains a Quality Manual that provides a detailed description of quality assurance (QA) and quality control (QC) policies and procedures for all toxicity testing and chemical analyses performed by PER. These policies and procedures apply to all aspects of toxicity testing that can potentially affect data quality and interpretation, including, but not limited to, sampling and handling of test materials, collection, holding, and conditioning of test organisms, test conditions and procedures, calibration of instruments, experimental design, reference toxicant testing, record keeping, and statistical evaluation of data.

The primary objective of PER management is to ensure that all of the data generated and reported are scientifically valid, legally defensible, and of known accuracy, precision, representativeness, and comparability. In accordance with this objective, the PER Technical Managers require that:

- All personnel concerned with environmental testing are familiarized with this Quality Manual and implement the policies and procedures in their work;
- All personnel are free from undue pressures, which might adversely affect the quality of work;
- All data is reviewed relative to method requirements and the Quality Manual. Corrective actions are implemented when data fail to meet established quality control criteria;
- Standard operating procedures have been developed in accordance with test methods established by the U.S. Environmental Protection Agency (USEPA), ASTM, and Standard Methods and are used in order to ensure that good quality data is collected; and
- All final reports are reviewed in order to meet the clients' objectives with respect to quality and completeness.

The scientific staff is composed entirely of degreed professional scientists experienced in performing both routine and regulatory testing, and many of the scientists have extensive expertise in research and methods development for more specific non-routine studies. Management and technical personnel have the authority and resources to carry out their duties and have procedures to identify and correct departures from the laboratory's management

system. Personnel understand the relevance and importance of their duties as related to the maintenance of PER's management system.

The experienced staff, the modern facility, and strict adherence to the policies and procedures described in the Quality Manual contribute to an overall commitment to timely production of the highest quality product and services in compliance with the TNI Standard. PER continually looks to improve the effectiveness of the management system through regular reviews and revisions to the Quality Manual.

As a result of the exceptional quality of the data, PER provides technical support related to NPDES, Water Quality Criteria Development, 404 Certification (Dredging), Ecological Risk Assessment, ambient monitoring, and product/chemical registration programs.

Table of Contents

Page

Appendices

List of Figures

Acronyms

USACE	Army Corps of Engineers
ASTM	American Society for Testing Materials
CBI	confidential business information
cm	centimeter
COC	chain-of-custody
CV	coefficient of variation
°C	degrees Celsius
DMR-QA	Discharge Monitoring Report – Quality Assurance
DO	dissolved oxygen
DOC	demonstration of capability
DTSC	Department of Toxic Substances Control
DQO	data quality objective
ECx	effective concentration in X% of the population.
EDD	electronic data deliverable
ELAP	Environmental Laboratory Accreditation Program
ELISA	enzyme linked immunosorbent assay
g/L	grams per liter
ICx	inhibitory concentration in X% of the population.
ISO/IEC	International Organization for Standardization/International Electrochemical Commission
LCx	lethal concentration in X% of the population.
mg	milligram
mg/L	milligram per liter
mL	milliliter
SDS	safety data sheet
NELAC	National Environmental Laboratory Accreditation Conference
NELAP	National Environmental Laboratory Accreditation Program
NIST	National Institute of Standards and Technology
NPDES	National Pollutant Discharge Elimination System
PAR	photosynthetically active radiation
PER	Pacific EcoRisk
ppt	parts per thousand
psu	practical salinity unit
PT	proficiency test(ing)
QA	quality assurance
QAPP	Quality Assurance Project Plan
QC	quality control
SAP	Sampling and Analysis Plan
SI	International System of Units

SOP	standard operating procedure
SWAMP	Surface Water Ambient Monitoring Program
TIE	toxicity identification evaluation
TNI	The NELAC Institute
µS	microsiemen
USEPA	United States Environmental Protection Agency

1. INTRODUCTION

This Quality Manual defines the policies, procedures, and documentation that ensure Pacific EcoRisk's testing services continually meet a defined standard of quality that is designed to provide clients with data of known and documented quality and, where applicable, demonstrate regulatory compliance.

This Quality Manual sets the standard under which all laboratory operations are performed, including the laboratory's organization, objectives, and operating philosophy. The Quality Manual has been prepared to ensure compliance with the 2016 TNI Environmental Laboratory Sector Standard – Volume 1 – Management and Technical Requirements for Laboratories Performing Environmental Analysis (EL-V1M1 through M7; ISO-2005). It is also compliant for PER's accreditations through the Oregon Health Authority's Environmental Laboratory Accreditation Program, the California Department of Public Health's Environmental Laboratory Accreditation Program (ELAP), and the Washington Department of Ecology (Appendix A). In addition, the policies and procedures outlined are compliant with the various accreditation and certification programs that PER maintains. A glossary of terms used in this Quality Manual is provided in Appendix B.

The Quality Manager is responsible for maintaining the currency of the Quality Manual. The Quality Manual is reviewed annually by the Quality Manager and his/her designees to ensure it still reflects current practices and meets the requirements of any applicable regulations, certifications, accreditations, or client specifications.

The Quality Manual is considered confidential within PER and may not be altered in anyway except by approval of the Technical Manager(s). If it is distributed to external users, it is for the purpose of reviewing PER's management system and may not be used for any other purpose without written permission.

PER's scope of testing services includes testing under the following regulatory programs/study areas: NPDES, Water Quality Criteria Development, 404 Certification (Dredging), Ecological Risk Assessment, ambient monitoring, and product/chemical registration programs. The scope of testing follows methods listed in Appendix C.

2. ORGANIZATION

PER is a commercial laboratory located in Fairfield, CA. The laboratory is a legally defensible organization and is responsible for carrying out toxicity testing activities that:

- Meet the requirements of the TNI Standard;
- Conform to the specifications and requirements of the methods and procedures for which the laboratory is certified to perform;

- Meet the requirements of the client, regulatory agencies (*e.g.*, USEPA, Regional Water Quality Control Boards, USACE, DTSC, etc.), and accrediting bodies through application of the policies and procedures outlined in this Section and throughout the Quality Manual; and
- Ensure the protection of its clients' confidential information and proprietary rights.

The organizational structure of the company and the relationship between quality management, technical operations, and administrative support services is summarized in Figure 2-1.

The job descriptions, roles, responsibilities, and authority of laboratory management are described in Section 3. The organizational chart specific to laboratory operations and job descriptions for all other staff can be found in Section 18.

2.1 Conflict of Interest and Undue Pressure

PER ensures that it is impartial and that personnel are free from undue commercial, financial, or other pressures that might influence their technical judgment.

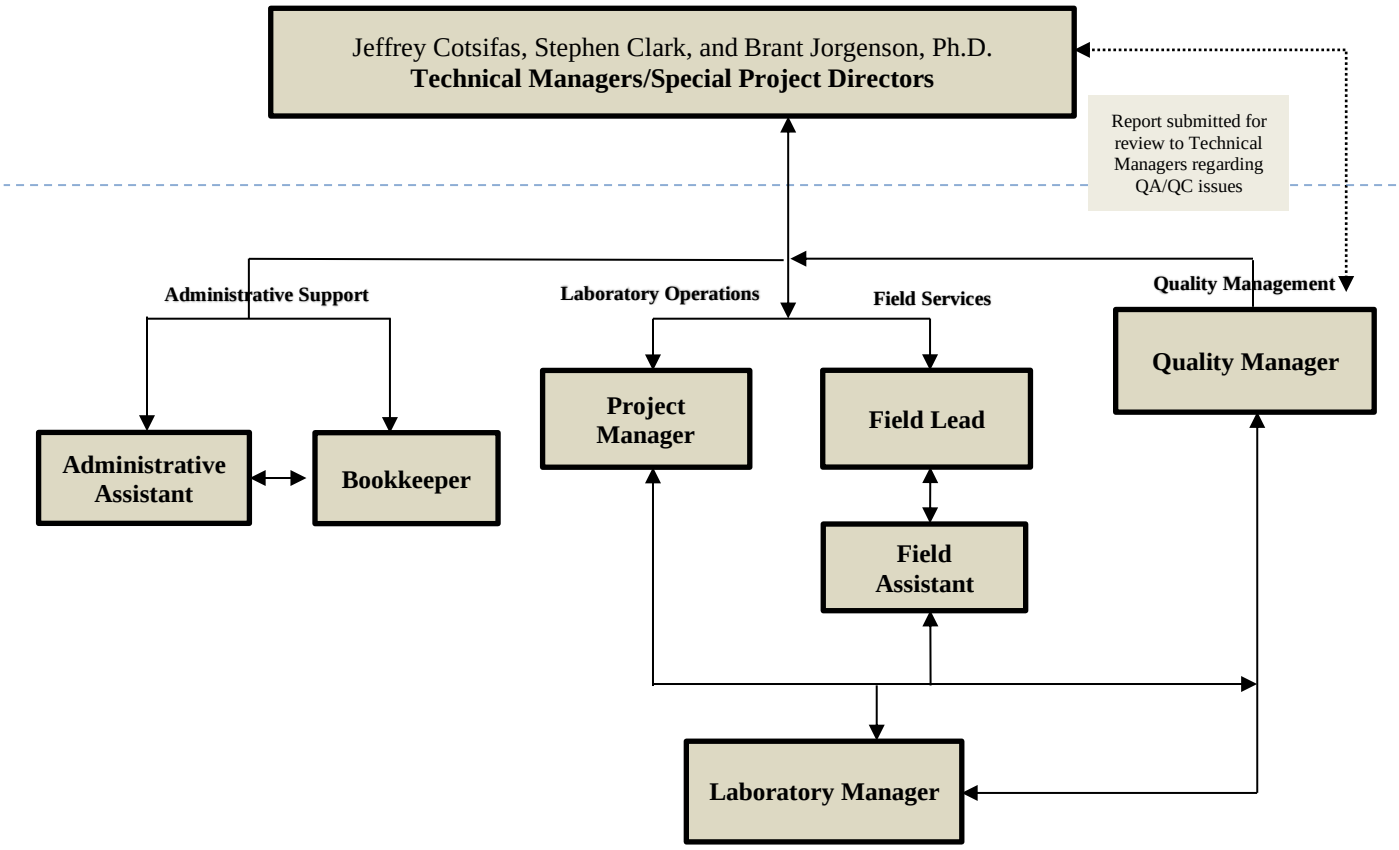
The company is organized in such a way that ensures conflicts of interest do not influence the technical judgment of analytical personnel. In addition, procedures are in place to prevent outside pressures or involvement in activities that may affect competence, impartiality, judgment, operational integrity, or the quality of the work performed at the laboratory.

Policies and procedures to prevent commercial, financial, or other influences that may negatively affect the quality of the work or negatively reflect on competence, impartiality, judgment, or operational integrity are described in depth in the **Statement of Scientific Integrity** and the **Employee Handbook**.

2.2 Client Confidentiality

All data, reports, and electronic deliverables generated by PER are considered confidential and proprietary to the client from whom the work has been contracted. It is the policy of PER that no employee shall share client information with any other party without expressed written guidance from the client. Electronic files are accessible on computers that require passwords from qualified PER staff. PER employees shall not participate in any activity that would compromise client confidentiality.

Figure 2-1. Company Organizational Chart



3. MANAGEMENT

PER has a well-defined management structure. Top management consists of the Technical Managers/Special Projects Directors. Additional management staff includes the Project Manager(s), Laboratory Manager(s), Field Manager(s), and the Quality Manager.

Management has overall responsibility for the technical operations and the authority needed to generate the required quality of laboratory operations. Management ensures communication within the organization maintains an effective management system and communicates the importance of meeting client, statutory, and regulatory requirements. Management ensures that the system documentation is known and available so that appropriate personnel can implement their part. When changes to the management system occur or are planned, managers ensure that the integrity of the system is maintained.

PER has appointed deputies for top managerial positions in the case when one of the managers is not in the office. Regarding the Technical Managers, another Technical Manager will act as a deputy to the absent Technical Manager.

Management's commitment to good professional practice and to the quality of its products is defined in the QA Policy Statement, which can be found on the first page of this document.

Management ensures that testing activities meet the requirements of the TNI Standards, the ISO/IEC 17025 Standard, and the needs of the client.

Management implements, maintains, and improves the management system and identifies noncompliance with the management system of procedures. Managers initiate actions to prevent or minimize noncompliance.

Management defines the minimal level of education, qualifications, experience, and skills necessary for all positions in the laboratory and ensures that technical staff has demonstrated capabilities in their tasks.

Management ensures technical competence of personnel operating equipment, performing tests, evaluating results, or signing reports and limits authority to perform laboratory functions to those appropriately trained and/or supervised. This is achieved through hiring staff with minimum education requirements, providing in-house training by senior staff, and requiring staff to read appropriate manuals and SOPs for their job description. Training is kept up to-date-as described in Section 18 by periodic review of training records and through employee performance reviews.

3.1 Management Roles and Responsibilities

Responsibilities and job descriptions of administrative staff and personnel who manage, perform, or verify work affecting the quality of toxicity tests is documented in this section and in Section 18. The job responsibilities for top PER management are as follows:

3.1.1 Technical Manager/Special Projects Director

The Technical Manager/Special Projects Director (and designees) provides the resources necessary to implement an effective quality and data integrity program. The Technical Manager/Special Projects Director is a full-time staff member who supervises laboratory operations and data reporting. The Technical Manager meets the general and education requirements and qualifications found in Sections 4.1.7.2 and 5.2.6.1 of the TNI Standard - EL-V1M2-2016. The Technical Manager's proof of experience in the fields of accreditation may be found in his/her employee file and resume.

If a Technical Manager is absent for fifteen (15) calendar days or more, a designee with appropriate qualifications will perform the Technical Manager's duties. Beyond a thirty-five (35) calendar day absence, management will notify the primary accreditation body in writing of the absence of the Technical Manager and the appointment of the designee.

PER Technical Managers are not the Technical Managers of more than one accredited environmental laboratory.

The Technical Manager/Special Projects Director is responsible for:

- Design and overseeing performance of individual projects;
- Overseeing all laboratory scientists participating in the project;
- Approval of and adherence to SOPs and the Quality Manual;
- Data interpretation;
- Preparation of final reports;
- Consultation daily with the Laboratory Manager and Quality Manager to evaluate laboratory operations;
- Overseeing general operation of the laboratory, including monitoring performance data and validity of operations;
- Implementation of any necessary corrective actions;
- Hiring of technical and administrative personnel;
- Procuring new clients;
- Reviewing invoices;
- Reviewing new contracts; and
- Requests and summarizes staff performance evaluations input for annual performance reviews for all personnel.

3.1.2 Quality Manager

The Quality Manager (and designees) is responsible for the oversight and review of quality control data and operates independently from the laboratory operations for which he/she has quality assurance oversight. The Quality Manager (and designees) is also responsible for the daily review of data generated by laboratory operations and generating QA/QC program reports for submittal to the Technical Manager(s) to ensure compliance with the TNI Standard. The Quality Manager's proof of experience in QA/QC procedures, knowledge of analytical methods, and the laboratory's management system may be found in his/her employee file and resume. The Quality Manager has the following responsibilities:

- Develops, reviews, and implements quality control policies and programs, including statistical procedures and techniques, for the maintenance of quality control standards;
- Revises and updates the Quality Manual on a regular basis, and as needed;
- Monitors quality assurance activities to determine conformance with the guidelines established in PER SOPs;
- Reviews and revises (as needed) PER SOPs at a minimum of at least every 2 years;
- Evaluates new ideas and current developments relative to the field of quality control and quality assurance and recommends the means for their implementation;
- Evaluates data quality and maintains records on related quality control charts and other pertinent information;
- Coordinates and/or conducts quality assurance investigations (*e.g.,* intra- and inter-laboratory programs);
- Reviews the overall QA/QC effort and reports issues to Technical Managers;
- Maintains a file of all laboratory accreditation information;
- Ensures the technical competence of technical staff;
- Assesses laboratory performance through control charts and proficiency testing, as well as performing annual audits;
- Evaluates data objectively and performs assessment without outside (*e.g.,* managerial) influence;
- Consults daily with the Laboratory Manager and Technical Managers to evaluate laboratory operations and reports deviations;
- Reviews all internal QC charts and outside QC programs to ensure that the quality of the data is maintained over time. Makes recommendations based upon these trends in order to consistently provide data that is of the highest quality;
- Manages non-conforming data evaluations, corrective action reports, and performance reports; and
- Contributes to staff performance evaluations.

3.1.3 Project Manager

Project Managers (and designees) prepare project quotes and proposals, study plans, QAPPs, and SAPs. Project Managers are responsible for communicating with clients, reporting results, tracking project performance and costs, and assuring that client deliverables meet required turn-around times. Project Managers contribute to staff performance evaluations. Project Managers represent PER at meetings and are familiar with outside projects.

3.1.4 Laboratory Manager

The Laboratory Manager (and designees) oversees daily operation of the laboratory. The Laboratory Manager coordinates activities of Project Managers and consults daily with Technical Manager(s) and Quality Manager to evaluate laboratory operations and review of new project requirements to ensure appropriate facilities and resources are available. The Laboratory Manager provides direction and guidance to scientists and laboratory assistants regarding planning of day and task completion. The Laboratory Manager limits authorization to perform laboratory functions to those appropriately trained and/or supervised and performs training of laboratory staff.

3.2 Documentation of Management/Quality System

The management system is defined through the policies and procedures provided in this Quality Manual and written laboratory Standard Operating Procedures (SOPs) and policies.

3.2.1 Quality Manual

The Quality Manual contains the following required items:

- Document title;
- Laboratory's full name and address;
- Name, address (if different from above), and telephone number of individual(s) responsible for the laboratory;
- Identification of all major organizational units that are to be covered by this Quality Manual and the effective date of the version;
- Identification of the laboratory's approved signatories;
- Signed and dated concurrence (with appropriate names and titles) of all responsible parties including the quality manager(s), technical manager(s), and the agent who is in charge of all laboratory activities, such as the laboratory director or laboratory manager;
- Objectives of the management system and contain or reference the laboratory’s policies and procedures;
- Laboratory’s official Quality Policy Statement, which shall include management system objectives and management’s commitment to ethical laboratory practices and to upholding the requirements of laboratory accreditation Standards; and
- Table of contents and applicable lists of references, glossaries, and appendices.

This Quality Manual contains or references all required elements as defined by the TNI Standard.

3.2.2 Standard Operating Procedures (SOPs)

A Standard Operating Procedure (SOP) is available for all laboratory procedures that require specific knowledge and/or adherence to a specific sequence of procedural steps. PER SOPs are reviewed and revised (as required) at a minimum frequency of once per year. The reviewed SOPs include, but is not restricted to, the following:

- Sample collection, preservation, and holding time;
- Sample custody, receipt, and document control;
- Analytical methods;
- Instrument calibration and maintenance;
- Test methods; and
- Sample holding and disposal.

All laboratory personnel participating in, or performing, any testing-related activity in the laboratory must be fluently familiar with the relevant SOPs. A copy of each SOP shall be maintained in each of the following locations:

- Staff Server;
- Office, in clearly-labeled binder(s); and
- Laboratory, in clearly labeled binder(s).

3.2.3 Order of Precedence

In the event of a conflict or discrepancy between policies, the order of precedence is as follows unless otherwise noted:

- Quality Manual;
- SOPs and Policies; and
- SAP, Study Plan, and Client Communications.

4. DOCUMENT CONTROL

All documents that are part of the document control system of the laboratory (*e.g.,* SOPs) include a date when the procedure was effective, and electronic copies are write-protected to prohibit unauthorized revisions. The QA/QC documents are periodically reviewed and revised as necessary to ensure continuing suitability with the applicable method; old records are moved to the QA/QC Program server (which can only be accessed by management and the QA staff) where the documents will be retained as historical records for at least five years. Technical Manager(s) must approve any revision to any QA/QC documentation. All old document control system documents have a revision number, a date that the document was put into effect, and a date once the document was no longer in effect.

A master list of all QA/QC documents related to the PER Quality Manual is maintained so as to identify the current revision status of each document. Copies of the approved QA/QC documents are available on the Staff server and in the office and laboratory; obsolete versions of the hard copy documents are promptly removed from all points of use and shredded, and obsolete electronic copies are placed on the QA/QC Program server (see above). Obsolete documents retained for legal or knowledge preservation are suitably marked as obsolete and stored in the PER library. Revised QA/QC documents have altered text identified in the "History of Change" section, are edited using track changes software, and are reviewed by the Technical Manager(s); approved documents are re-issued as soon as practicable.

5. REVIEW OF REQUESTS, TENDERS, AND CONTRACTS

Prior to accepting a new project, the Technical Manager(s) review the scope of the project to determine if it is consistent with the services provided by PER, including a review of the requested methods, certifications/accreditation, requirements for laboratory facilities, and available laboratory and staff resources. Should the review indicate any potential conflict or deficiency, the Technical Manager(s) will discuss such limitations with the requesting party. The use of non-standard methods is subject to an agreement between PER and the client, and will include a written request (*e.g.*, contract or scope of work) from the client prior to the use of non-standard methods. Projects will only be accepted that can be properly completed with the laboratory resources. Any differences between the request for services and a formal contract are resolved prior to initiation of the project in the form of a tender and must be acceptable to both parties in writing. When both parties accept the request and tender a contract, the project will then be initiated. Records of all conversations and e-mail related to requests for services are maintained by the Technical Manager(s) and are placed in the contract/client file when appropriate. Records are maintained for every contract or work request, when appropriate. Upon project completion, a Technical Manager reviews test reports to determine if conditions outlined in the contract have been met. Clients are informed of any deviations from a contract.
Following the review of a request for services, the Technical Manager(s) or Project Manager prepares a **Test Order Form**, and a project number and test folder are generated for the project. The project number is used to track all project-associated data and the test folder is used to contain relative documentation required for each specific project. The Technical Manager(s) or Project Manager prepares all of the necessary data sheets for the testing required for the project, ensures that sample collection and delivery are coordinated with the client, orders test organisms when necessary, and transfers the test folder to the laboratory.

For projects that include field sampling, the project management role may vary (PER or the client generates a SAP and/or field log that specifies work to be performed that is consistent with the project contract and QAPP). For a project managed by PER, the Technical Manager or Project Manager prepares the SAP and field logs, which are provided to the field scientists that

will perform the sampling. The Project Manager or field scientists will ensure that the supplies specified in the field log are ordered and arrive in time to perform the sampling.
All project-related communications with the client, including e-mails, fax, and telephone conversations, are maintained by the Technical Manager(s) and Project Manager in one or more of the following locations:

- E-mail program files on the Technical Manager(s) or Project Manager's computer;
- Telephone conversations are documented in phones logs or laboratory notebooks; and
- Hard copies of fax or e-mail communications are maintained in the project folder.

6. SUBCONTRACTING OF ENVIRONMENTAL TESTS

A subcontract laboratory is defined as a laboratory external to PER, or at a different location than the address indicated on the front cover of this manual, which performs analyses for this laboratory. Toxicity tests for which PER is certified are generally not subcontracted; only analytical samples in support of toxicity tests or monitoring programs PER oversees are subcontracted.

When subcontracting analytical services, PER ensures that work requiring accreditation is placed with an appropriately accredited laboratory or one that meets applicable statutory and regulatory requirements for performing the tests. When PER has the flexibility to select the subcontractor, preference is given to NELAP accredited laboratories. The Quality Manager maintain a list of subcontract laboratories. On an annual basis, the subcontract laboratories are required to submit the following documentation that is maintained on the PER server:

- Quality Manual;
- Results of recent proficiency testing;
- Results of their most recent audit;
- Statement of qualifications; and
- Laboratory accreditation certificate, including fields of testing/analysis.

The Technical Manager(s) or their designees notifies the client of the intent to subcontract the work in writing. When possible, the laboratory gains the approval of the client to subcontract their work prior to implementation, preferably in writing. The laboratory performing the subcontracted work is identified in the final report. PER assumes responsibility to the client for the subcontractor's work, except in the case where a client or a regulating authority specified which subcontractor is to be used.

7. PURCHASING SERVICES AND SUPPLIES

The laboratory ensures that purchased supplies and services that affect the quality of environmental tests are of the required or specified quality by using approved suppliers and products.

The laboratory has procedures for purchasing, receiving, and storage of supplies that affect the quality of environmental tests. The Administrative Assistant maintains the list of approved suppliers of services and supplies and the Technical Manager overseeing the quality management team or his/her designees approves technical content of purchasing documents prior to ordering.

Policies for receipt of supplies are documented in the **Incoming Supplies and Equipment Approval Checklist**. The purchased supplies and reagents must be identical with those noted on the packing slip (*e.g*., class, grade, and amount) and are inspected or otherwise verified on this checklist as complying with requirements defined in the test method. Chemicals are further checked for storage conditions on the Safety Data Sheet (SDS) and stored accordingly in the laboratory. The checklist and supporting manufacturers documentation are maintained in the **Incoming Supplies and Equipment Approval Checklist** binder in the laboratory.

Records for equipment maintenance, calibration, or certificates of analyses are stored with the appropriate equipment log.

8. SERVICE TO THE CLIENT

PER provides its clients, or their representatives, with full cooperation when a request is made to clarify a client's testing request and to monitor the laboratory's performance in relation to the work performed, provided that confidentiality is maintained for testing performed for other clients.

8.1 Client Confidentiality

The laboratory confidentiality policy is to not divulge or release any information to a third party without proper authorization. Third party requests for data and information are referred to the client. Data and records identified as proprietary, privileged, or confidential are exempt from disclosure. All electronic data (storage or transmissions) are kept confidential, based on technology and laboratory limitations, as required by client or regulation. When necessary, confidentiality statements are used in e-mails and documents.

8.2 Client Support

Communications with the client, or their representative, are maintained to provide proper instruction and modification for testing. Technical staff are available to discuss any technical questions or concerns the client may have. The client, or their representative, may be provided reasonable access to laboratory areas for witnessing testing.

The Technical Manager(s) or Project Manager communicate delays or major deviations to the testing to the client immediately.

The Technical Manager(s) or Project Manager will provide the client with all requested information pertaining to the analysis of their samples. An additional charge may apply for additional data/information that was not requested prior to the time of sample analysis or previously agreed upon.

8.3 Client Feedback

The laboratory routinely seeks both negative and positive feedback by including an optional survey link in all e-mail communications from Technical Managers and Project Managers. Feedback provides acknowledgement, corrective actions where necessary, and opportunities for continuous improvement. Client feedback is solicited via e-mail and a client survey.

9. COMPLAINTS

PER's policy is to document and respond to any complaints filed by a client or other parties about the laboratory activities. Where a complaint, or any other circumstance, raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or the TNI Standard requirements, or concerning the quality of the laboratory testing, the Technical Manager(s) ensure that those areas of activity and responsibility are promptly audited. This may include tracking of quality checks, internal audits, a quality control assessment, and corrective action implementation and monitoring. In addition, a **Preventative Action** form may be completed by staff to minimize a future occurrence. Records of the complaint and subsequent actions are maintained in the QA/QC Program files in the laboratory.

10. CONTROL OF NON-CONFORMING ENVIRONMENTAL TESTING WORK

Non-conforming work is work that does not meet acceptance criteria or requirements. Non-conformances can include departures from standard operating procedures or test methods or unacceptable quality control results (see Section 23). Identification of non-conforming work can come through client complaints, quality control, instrument calibration, evaluating consumable

materials, staff observation, final report review, management reviews, and internal and external audits.

10.1 Exceptionally Permitting Departures from Documented Policies and Procedures

Requests for departures from laboratory procedures are approved by the Technical Manager(s), confirmed with the Quality Manager, and are documented in the same fashion as other client communications as outlined in Section 5. Planned departures from procedures or policies do not require audits or investigations.

10.2 Non-Conforming Work

PER's policy for control of non-conforming work is to identify the non-conformance, determine if it will be permitted, and take appropriate action. The Quality Manager and his/her designees oversee proper communication of non-conforming work and implementation of the applicable procedures associated with non-confirming work.

The investigation and associated corrective actions of non-conforming work involving alleged violations of the company's Data Integrity and Ethics Program follow the procedures outlined in Section 17.

Corrective actions for routine, one-time non-conformances, such as transcription errors, may be documented on raw datasheets, logbooks, e-mail, or deviation from protocol sheets. The Quality Manager documents more serious corrective actions (non-conforming work that could reoccur or where there is doubt that the laboratory is following its own policies or procedures) by using a more formal corrective action form. The procedure for investigating and taking appropriate corrective actions of non-conforming work are described in Section 12.

PER evaluates the significance of the non-conforming work and takes corrective action immediately. The client is notified if their data has been impacted. The laboratory allows the release of non-conforming data only with approval by the Technical Manager(s) on a case-by-case basis. Reports reflect any non-conforming work that is deemed conditionally acceptable based on the "best professional judgment" of the Technical Manager(s) when the degree of departure did not affect the outcome of the test.

The discovery of a non-conformance for results that have already been reported to the client must be immediately evaluated for significance of the non-conformance, if the data is acceptable to the client, the appropriate corrective action will be determined.

10.3 Stop Work Procedures

For any non-conforming testing, it is PER's policy that the Laboratory Manager and/or Quality Manager must immediately notify the Technical Manager(s) so that the significance of the non-conforming work can be evaluated, and work can be stopped if deemed appropriate by the Technical Manager(s). After work has been stopped, the Technical Manager(s) authorizes the resumption of work. The evaluation of the issue, root cause, and resolution of the corrective action are documented in an "Evaluation of Non-Conforming Data" report.

11. IMPROVEMENT

Improvement in the overall effectiveness of the laboratory and field activities management system is a result of the implementation of the various aspects of PER's management system: quality policy and objectives (Section 3), internal auditing practices (Section 15), the review and analysis of data (Section 23), the corrective action (Section 12) and preventive action (Section 13) processes, and the annual management review of the quality management system (Section 16) where the various aspects of the management/quality system are summarized and evaluated and where plans for improvement are developed.

12. CORRECTIVE ACTION

Corrective action is the action taken to eliminate the causes of an existing non-conformity, defect, or other undesirable situation in order to prevent recurrence. Deficiencies cited in external assessments, internal quality audits, data reviews, client feedback/complaints, control of non-conforming work, or managerial reviews are documented and are followed by corrective action. Corrective actions taken are appropriate for the magnitude of the problem and the degree of risk.

Sample data associated with a failed quality control (*i.e.*, failed to meet test acceptability criteria, etc.) are evaluated for the need to be reanalyzed or qualified. Unacceptable quality control results are documented and an evaluation is performed and documented in an "Evaluation of Non-Conforming Data" report. If a corrective action is determined to be necessary based on the results of this investigation, it is implemented following the procedures outlined in this section. The Technical Manager(s) review "Evaluation of Non-Conforming Data" reports and suggest improvements, alternative approaches, and procedures where needed. If the data reported are affected adversely by the non-conformance, the affected data is clearly identified in the report and the client is notified.

Procedures for corrective actions associated with audits are discussed in Section 15 but follow the same general procedures outlined here.

12.1 General Procedure

Corrective actions start with assessment of the cause of the problem. PER uses an "Evaluation of Non-Conforming Data" report to document and track investigations of non-conforming work and, where necessary, as documentation of implementation and monitoring of corrective actions. The Quality Manager and his/her designees are responsible for initiating corrective actions on routine data reviews where a non-conformance is found that could reoccur or where there is doubt about the compliance of the laboratory to its own policies and procedures. All deficiencies are investigated, and a corrective action plan is developed and implemented if determined to be necessary. The Quality Manager and his/her designees monitor the effectiveness of corrective actions.

12.1.1 Cause Analysis

When failures due to systematic errors have been identified, the first step of the corrective action process starts with the initial investigation and determination of root cause(s) of the problem. Records are maintained of non-conformances requiring corrective action to show that the root cause(s) was investigated and to show the results of the investigation. These evaluations are documented in an "Evaluation of Non-Conforming Data" report and are maintained by the Quality Manager and his/her designees (See Section 10). They are located on the QA/QC Program server and are available only to authorized personnel who have been granted access to this server.

Where there may be non-systematic errors and, as such, the initial cause is readily identifiable or expected random failures (*e.g.,* failed quality control), a formal root cause analysis is not performed, and the process begins with selection and implementation of corrective action.

12.1.2 Selection and Implementation of Corrective Actions

Where uncertainty arises regarding the best approach for analysis of the cause of non-conformances that require corrective action, appropriate personnel (*e.g.,* Quality Manager, Laboratory Manager) will recommend corrective actions that are appropriate to the magnitude and risk of the problem and that will most likely eliminate the problem and prevent recurrence. The Technical Manager(s) and their designees ensure that the corrective actions are implemented within the agreed upon time frame.

12.1.3 Monitoring of Corrective Actions

The Quality Manager will monitor implementation and documentation of the corrective action to ensure that the corrective actions were effective. Monitoring of corrective actions may include an audit, where necessary (see Section 15).

13. PREVENTATIVE ACTION

PER promotes a workplace environment that encourages critical thinking and observation skills by its scientists and assistants. As part of the PER QA/QC program, we encourage scientists and assistants to be proactive and complete a **Preventative Action** form to propose changes to our QA/QC program that will result in improvements in the quality of work or to reduce sources of non-conformance with the current QA/QC program. The Technical Manager(s) review any submitted **Preventative Action** form during their weekly Management Meeting and work with an individual scientist or assistant to develop an action plan to implement the proposed preventative action, should it be compatible with TNI Standard and have an acceptable cost for the proposed benefit. The Quality Manager tracks the revisions to the QA/QC program to ensure that they are effective.

14. CONTROL OF RECORDS

The laboratory maintains a record system appropriate to its needs, records all laboratory activities, and complies with applicable standards or regulations as required. The record system is designed to produce unequivocal, accurate records that document all laboratory activities. Records allow for the historical reconstruction of laboratory activities related to sample handling and analysis and help establish factors affecting the uncertainty of the test and enable test repeatability under conditions as close as possible to the original. Data is recorded immediately and legibly in permanent black ink. Corrections are initialed and dated. A single line strikeout is used to make corrections so that the original record is not obliterated. A **Comments and Observation** form should be completed with the reason for corrections.

14.1 Records Maintained

At minimum, the Quality Manager (or designees) and/or Administrative Assistant maintain the following records:

- Original observations;
- Sample receiving and storage records (COCs, sample ID codes, etc.);
- Instrument and support equipment logbooks;
- Proficiency testing results;
- Calibration records;
- Demonstrations of capability;
- Project–specific correspondence relating to laboratory QC testing;
- Corrective action records including evaluations of non-conforming data;
- Preventative action records;
- Management reviews;
- Internal and external audits;
- Data review and verification records;

- Personnel qualification, experience, and training records;
- A record of names, initials, and signatures for all individuals who are responsible for signing or initialing any laboratory record; and
- A hard and electronic copy of each project report.

14.2 Records Management and Storage

All records are retained for a minimum of five years, which allows for a historical reconstruction of all laboratory activities. Hard copies of client reports containing original test data are filed alphabetically by client for each year, and electronic copies are stored by client on the PER server and accessible only by staff with authorized passwords for the server and desktop computers; the PER server is automatically backed up daily and electronic files can only be accessed by scientists through password-protected computers. Hard copies of all QA/QC files (*e.g.*, old log books, audits, management reviews, corrective actions, etc.) are stored in the "QA/QC Program" filing cabinets and/or electronically on the server in the "QA/QC Program" folder. Following the minimum five-year holding period for all files, the Technical Manager(s) must approve the disposal, via shredding or deletion from server, of any file; the QA and administrative staff maintain master lists of such files.

Records (including electronic records) are easy to retrieve, legible, and protected from deterioration or damage. Records are also held securely and in confidence and are available to accrediting bodies for a minimum of five years or as required by regulation or contract. Records that are stored only on electronic media are supported by the hardware and software necessary for their retrieval. Access to protected records is limited to management and their designees to prevent unauthorized access or amendment.

Additional information regarding control of data is included in Section 20.

14.3 Legal Chain-of-Custody Records

All samples that arrive at PER are treated as though the data generated using the sample may be used as legal evidence. Therefore, all samples are required to have a COC record that includes the client, client contact, sample ID, collected date and time, sample type (*e.g.*, freshwater, stormwater, sediment, etc.), sample volume, sample container type/size, tests required, and custody of the sample (*i.e.*, the signature of the person collecting/releasing the sample [and date and time relinquished] and the signature of the person receiving the sample [and date and time received]).

15. AUDITS

Audits measure laboratory performance and verify compliance with accreditation/certification and project requirements. Audits specifically provide management with an on-going assessment of the management system. They are also instrumental in identifying areas where improvement in the management/quality system will increase the reliability of data. Audits are of four main types: internal, external, performance, and system. Section 15.3 discusses the handling of audit findings.

15.1 Internal Audits

PER follows a schedule of internal audit tasks designed to be performed throughout the year such that all elements are audited on an annual basis. These audits verify compliance with the requirements of the management/quality system, including testing methods, SOPs, the Quality Manual, ethics policies, data integrity, other laboratory policies, and the TNI Standard. It is the responsibility of the Quality Manager (and his/her designees) to plan and organize audits as required by the schedule and requested by management. Wherever resources permit, trained and qualified personnel, who are independent of the activity to be audited, carry out these audits. The area audited, the audit findings, and corrective actions are recorded. Audits are reviewed after completion to ensure that corrective actions were implemented and effective.

15.2 External Audits

It is the laboratory's policy to cooperate and assist with all external audits, whether performed by clients or an accrediting body. Management ensures that all areas of the laboratory are accessible to auditors as applicable and that appropriate personnel are available to assist in conducting the audit. Findings of external audits are responded to within the time frame agreed to at the time of the audit.

15.2.1 Confidential Business Information (CBI) Considerations

During on-site audits, on-site auditors may come into possession of information claimed as business confidential. A business confidentiality claim is defined as "a claim or allegation that business information is entitled to confidential treatment for reasons of business confidentiality or a request for a determination that such information is entitled to such treatment". When information is claimed as business confidential, PER places on (or attaches to) the information a cover sheet, stamped or typed legend, or other suitable form of notice, employing language such as "trade secret", "proprietary", or "company confidential" at the time it is submitted to the auditor. Confidential portions of documents otherwise non-confidential are clearly identified. CBI may be purged of references to client identity by the responsible laboratory official at the time of removal from the laboratory. However, sample identifiers may not be obscured from the information.

15.3 Audit Findings and Corrective Actions

Internal or external audits may result in findings that cast doubt on the effectiveness of the laboratory operation to produce data of known and documented quality or that question the correctness or validity of sample results an investigation is performed. If corrective action is needed, the implementation of the corrective action and follow-up tracking of the effectiveness of the corrective action is documented. The responsibility for developing and implementing corrective actions to findings is the responsibility of the Quality Manager and his/her designees. Corrective actions are documented through the corrective action process described in Section 12. The Quality Manager (and his/her designees) prepare monthly audit reports that outline any internal audit findings, corrective actions, and monitoring of the effectiveness of the corrective actions. The monthly audit reports are reviewed by the Technical Manager(s). Documentation may also be in the form of a memo or an "Evaluation of Non-Conforming Data" report. Responses to comments and findings of external audits are communicated to the auditor.

Should the findings of an audit cast doubt on the quality of testing performed for a client, the client is notified in writing within 30 days of discovering the issue and is informed of the corrective action(s) that were implemented to address the problem; records of such client communications are retained in the affected project folders. Management ensures that this notification is carried out within the specified time frame.

Should an audit indicate that inappropriate actions were taken by PER staff that resulted in questions related to data integrity (See Section 17), the issue is handled in a confidential manner by the Technical Manager(s) and will include a full investigation, appropriate corrective action(s), documentation of the issue (signed and dated), a follow-up evaluation, and appropriate notification to affected client(s).

15.4 Additional Audits

In addition to the scheduled internal audits, it may sometimes be necessary to conduct special audits as a follow-up to corrective actions, proficiency testing (PT) results, complaints, regulatory audits, alleged data integrity issues, or when requested by the Technical Manager(s). This can also be done when a serious issue or risk to the laboratory has been identified.

Where the identification of non-conformances or departures from normal laboratory procedures casts doubt on PER's compliance with its own policies and procedures, or its compliance with the TNI Standard, the laboratory ensures that the appropriate areas of activity are audited as soon as possible. These audits address specific issues. The area audited, the audit findings, corrective actions, and monitoring of corrective actions are recorded.

PER's management system is audited though annual management reviews. Refer to Section 16 for further discussion of management reviews.

16. MANAGEMENT REVIEWS

PER top management (as defined in Section 3) performs an Annual Management Review during the first quarter of each year. This program includes a review of the laboratory management and quality systems and environmental testing activities to ensure continuing suitability and effectiveness in achieving the TNI standard and implements any necessary changes to improve on the quality of testing and client services. The program consists of an evaluation of:

- The suitability of policies and procedures;
- Reports from managerial and supervisory personnel;
- Outcomes of internal audits, external audits, and assessments by external bodies;
- A review of corrective and preventative actions;
- Results of inter-laboratory comparison and proficiency testing;
- Changes in the volume and type of work;
- Client feedback;
- Client complaints;
- Recommendations for improvement; and
- Other relevant factors, such as quality control activities, resources, and staff training.

The Annual Management Review is documented with an "Annual Management Review" report, for which an electronic copy is stored on the Owner and QA/QC Program servers. Two copies are prepared, one including Confidential Business Information (CBI) for in-house use (located on the Owner server) and one with CBI excluded for public use (located on the QA/QC Program server). Any actions recommended in the Annual Management Review Report are implemented within 60 days of the completion of the report.

Findings and follow-up actions from Annual Management Reviews are recorded in the "Annual Management Review" report.

17. DATA INTEGRITY AND ETHICS PROGRAM

Pacific EcoRisk is committed to ensuring the integrity of our data and providing valid data and documented quality to our clients. Upon hiring and during an annual staff meeting, each employee is required to read the **Statement of Scientific Integrity** and acknowledge, understand, and agree to their personal ethical responsibilities and legal responsibilities, including potential punishment and penalties for improper, unethical, or illegal actions.

17.1 Ethics and Integrity Training

PER maintains a Data Integrity Training Program that is documented in writing, and includes an overview of the company mission, relationship to the critical need for honesty and full disclosure in reporting results, how and when to report data integrity issues, and a description of the record keeping required under the program. Employees are informed that any infractions of the program can result in immediate termination and could result in civil/criminal prosecution. Attendance for both the orientation and annual meetings are documented via a signed certification from each staff member that they understand their obligations related to data integrity. Records of this training are maintained in personnel files and in the Data Integrity Program file on the QA/QC Program server. The Technical Manager(s) fully support these procedures and are integrally involved with the implementation of the program.

17.2 Improper Actions

Improper actions are defined as deviations from contract-specified or method-specified practices and may be intentional or unintentional. Unethical or illegal actions are defined as the deliberate falsification of analytical or quality assurance results where failed method or contractual requirements are made to appear acceptable. Prevention of improper, unethical, or illegal actions in the laboratory begins with the zero-tolerance policy established by the Technical Manager(s).

17.3 Prevention and Detection Program for Improper, Unethical, or Illegal Actions

The PER management maintains a proactive program for the prevention and detection of improper, unethical, or illegal activities. The program includes:

- An ethics policy that is read and signed by all personnel;
- Initial and annual ethics training;
- Internal audits;
- Inclusion of anti-fraud language in subcontracts;
- Analyst notation and sign-off on manual integration changes to data;
- "No-fault" policy that encourages laboratory personnel to come forward and report ethical, data integrity, or fraudulent activities; and
- Assessment of data integrity performed by Quality Manager during the daily program review.

17.4 Investigation of Ethics Violations or Data Integrity Violations

The Quality Manager serves as the PER Data Integrity Officer, to whom laboratory personnel can report improper, unethical, or illegal practices. The PER Technical Manager(s) will perform a full investigation should any ethical or data integrity violations occur. The outcome of the investigation may result in immediate suspension or termination or may result in civil/criminal

prosecution. Clear documentation of the investigation is maintained and the need for any further detailed investigation (*e.g*., civil/criminal prosecution) is clearly documented.

17.5 Annual Review of Data Integrity Program

The Data Integrity Program is reviewed annually by the Technical Manager(s) during the Annual Management Review and is modified, as necessary.

17.6 Client Notification

A Technical Manager will notify a client in writing in all cases when data quality is impacted by non-conformance to testing protocols; re-testing would be performed, if necessary. Furthermore, a Technical Manager would notify the client in writing when any aspect or result of the environmental testing work does not conform to the agreed requirements specified by the client.

18. PERSONNEL

PER employs competent personnel based on education, training, professional experience, and demonstrated skills, as required. All personnel are responsible for complying with all QA/QC requirements that pertain to their organizational/technical function. All personnel who are involved in activities related to sample collection, sample analysis, evaluation of results, or who sign test reports must demonstrate competence in their area of responsibility. Appropriate supervision is given to any personnel in training and the trainer is accountable for the quality of the trainee's work. Personnel are qualified to perform the tasks they are responsible for based on education, training, experience, and demonstrated skills as required for their area of responsibility.

Key laboratory operations positions include the Laboratory Manager, Quality Manager, Project Managers, Field Leads, Scientist I, II, and III (possess academic or work background in the field of aquatic toxicology), and Laboratory Assistant I, II, and III; an outline of the laboratory operations organizational chart is depicted as a flow-chart in Figure 18-1. Individuals filling these jobs have the required training, degree, and/or professional experience to meet the job responsibilities (*e.g.,* Scientist I, II, and III are required to possess a minimum of a BS degree). In the event that contracted support staff are used, they are trained in the method and related laboratory control system and are supervised by a trained scientist at a higher job level and/or the Laboratory Manager.

Figure 18-1. Laboratory Operations Organizational Chart

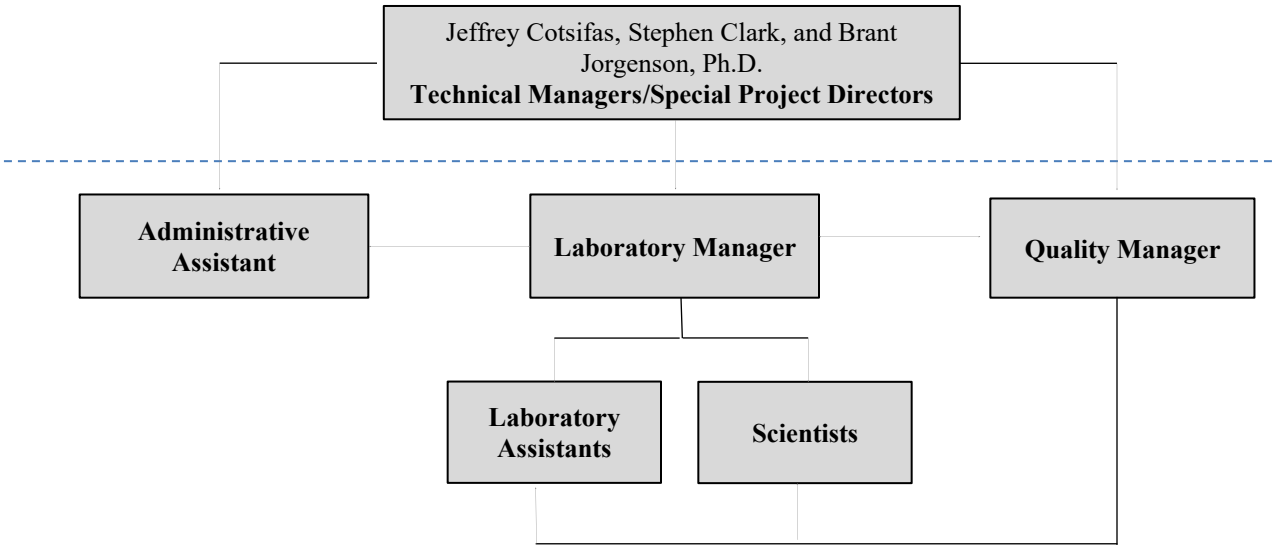
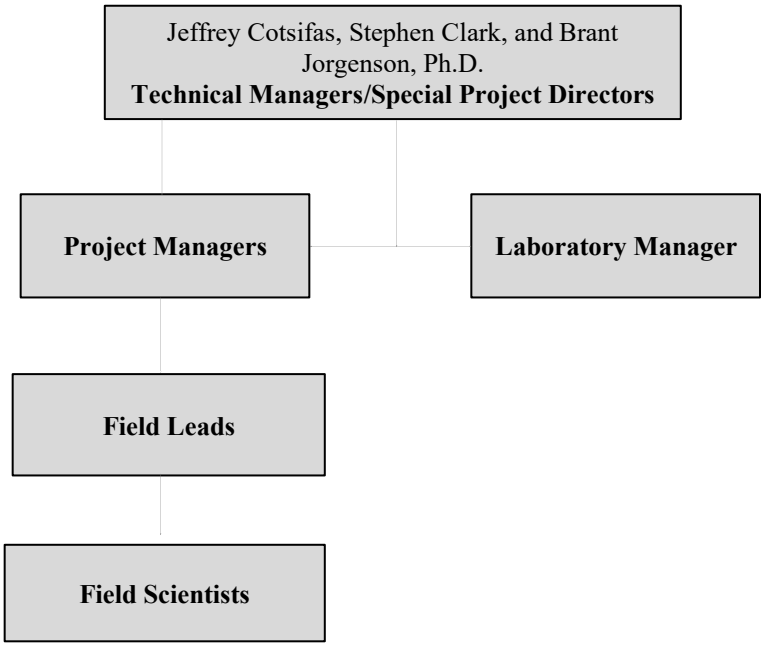


Figure 18-2. Field Operations Organizational Chart



18.1 Personnel Roles and Responsibilities

The job responsibilities for each member of PER management are outlined Section 3. An outline of the company organization is presented in Section 2 and is depicted as a flowchart in Figure 2-1. Job responsibilities for administrative, field, and laboratory staff are as follows:

18.1.1 Administrative Assistant

The Administrative Assistant provides administrative support for all projects, assists Quality Manager in maintenance of records, and prepares reports for delivery to clients.

18.1.2 Bookkeeper

The Bookkeeper prepares all accounts receivable and accounts payable records. The Bookkeeper prepares all client invoices, maintains client contracts/quotes, and provides contract support.

18.1.3 Laboratory Assistant I

Laboratory Assistant I staff are responsible for sample pick-up and log-in, completion of chain-of-custody records, shipping, cleaning of all glassware, performance of water quality analyses, preparation of synthetic waters, weight determinations, processing samples, animal husbandry, etc. Laboratory Assistant I staff maintain unencumbered laboratory work areas through regular cleaning and organization.

18.1.4 Laboratory Assistant II

Laboratory Assistant II staff may provide maintenance of *Ceriodaphnia* and daphnid cultures, and may participate in scoring of embryo development tests. Additionally, they may participate in all aspects of routine acute freshwater and marine toxicity testing, including solution preparation. These staff members may perform daily calibration and maintenance of water quality meters. These staff members also possess the skills of the Laboratory Assistant I position.

18.1.5 Laboratory Assistant III

Laboratory Assistant III staff are responsible for performing all aspects of routine chronic *Ceriodaphnia dubia* and *Pimphales promelas* toxicity testing, including solution preparation. These staff members may also participate in any required daily feeding of test organisms and cultures. These staff members also possess the skills of the Laboratory Assistant II position.

18.1.6 Scientist I

Scientist I staff are responsible for the daily performance of the following tests: acute and chronic freshwater and estuarine/marine invertebrates and fish. Scientist I staff are responsible for the daily performance of these tests, including data acquisition, recording, review, and analyses. When necessary, Scientist I staff provide sample manipulations (*e.g.*, pH adjustment, zeolite treatment, de-chlorination, etc.) necessary to perform testing. Scientist I staff perform the statistical analyses of test results and prepare electronic data deliverables (EDDs). Scientist I staff

may write reports for the methods/tests that they are certified to perform. Scientist I staff participate in field sampling projects and are familiar with field sampling procedures and operation of field equipment.

18.1.7 Scientist II

Scientist II staff are responsible for the daily performance of the following tests: embryo development, freshwater/marine sediment, and freshwater/marine algal growth. Scientist II staff are responsible for the daily performance of these tests, including data acquisition, recording, review, and analyses. When necessary, Scientist II staff provide more technical sample manipulations (*e.g.* TIE manipulations) necessary to perform testing. Scientist II staff perform the QA review of statistical analyses of test results. Scientist II staff write reports for the methods/tests that they are certified to perform. Scientist II staff manage analytical samples that are submitted to subcontract laboratories. Scientist II staff possess the skills of the Scientist I position.

18.1.8 Scientist III

Scientist III staff are responsible for technical testing, including the performance of Toxicity Identification Evaluations (TIE), enzyme-linked immunosorbent assay (ELISA) analyses, and water effects ratio testing (WER). Scientist III staff provide proactive planning with Field and Laboratory Managers, logistical support for planning testing, and coordinate activities with Laboratory Assistants. Scientist III staff write reports for the methods/tests that they are certified to perform. Scientist III staff possess the skills of the Scientist II position.

18.1.9 Field Lead

Field Leads are familiar with SAPs for field sampling projects and participate in, oversee, and organize field-sampling events. They lead sampling teams in the field with oversight from Project Managers. Field Leads possess, at a minimum, the skills of the Scientist I position.

18.2 Training

Based on the job descriptions described above, PER hires Laboratory Assistants and Scientists that have appropriate academic and/or professional experience to perform the tasks for their given job classification. The Technical Directors maintains these records in the employee files for experience prior to employment at PER. In addition, PER has an extensive training program to ensure that each Assistant and Scientist is trained in the specific methods necessary to perform their job under the Quality Program. Prior to participation in any testing, field activity, or analyses, the Scientists and Assistants are required to read the SOPs and appropriate manuals that describe tasks that are part of their job description; all staff members must also read and be familiar with the Quality Manual.

Hands-on training involves an experienced staff member demonstrating all aspects of the method for the inexperienced staff member. This training is documented in their training log. When warranted (*e.g.,* it is their first time handling that type of organism, the species is sensitive to handling stress, there is an aspect of the test that they have not participated in with other organisms, etc.), the inexperienced staff member is required to demonstrate capability in performing a test or analysis with oversight by an experienced staff member by performing a Demonstration of Capability (DOC) test in which they perform as much of the test as possible (*i.e.,* if the test duration is longer than 5 days, another scientist will need to maintain it while the staff member is on his/her weekend). The Quality Manager reviews the DOC test and approves/disapproves the staff member for the associated test or analysis. If not approved, the Quality Manager will schedule a retraining session with the staff member, and they will perform a second DOC test. The training program is viewed as an ongoing process as staff continue to take on additional responsibilities as they develop professionally.

Since the duration of many toxicity tests is greater than the standard workweek (*i.e.,* staff do not solely perform a toxicity test from test initiation to termination), ongoing demonstrations of capability by staff must focus on individual adherence to the QA/QC Program. In order to maintain their ongoing DOC, staff members with < 3 years of experience in their job position at PER are required to maintain their continued proficiency through yearly participation in test initiation, test maintenance, and test termination for each test that the analyst is certified to perform. Analysts document continued proficiency training in their continued proficiency log. This information is used to establish the DOC for each method at the beginning of each year. Analysts with ≥ 3 years of experience with the methods are not required to participate in each test method on a yearly basis given their advanced level of experience with the methods; such analysts are expected to review the SOPs prior to participating in the testing that they have not performed for some time (*i.e.,* 12 months).

Toxicity tests used to document initial and ongoing DOC must meet all test acceptability criteria specified in the EPA testing manuals in order to be considered acceptable for continued proficiency training.

“Group training workshops” are provided, as necessary, by a Laboratory Manager, Quality Manager, or Project Manager(s), and are documented, both in terms of content and attendance. These workshops may focus on a review of a given method, an introduction of a new method, or on the use of new equipment.

The Quality Manager (or designee) maintains the training log. The training log serves as the official record of capabilities for each staff member. The Technical Manager(s) are responsible for completing the training log for each staff member by signing the DOC sheets. Staff are required to record the date that they have completed the initial and ongoing DOC for a given method in their toxicity test training and proficiency logs. Detailed instructions related to

completion of toxicity test training and proficiency logs are provided in Section 20.

19. ACCOMMODATIONS AND ENVIRONMENTAL CONDITIONS

Successful evaluation of contaminated waters and sediments by PER is due, in no small part, to our state-of-the-art laboratory facilities. The laboratory, located in Fairfield, provides over 4,000 ft^2 of office and conference facilities and over 12,000 ft^2 of actual laboratory space for conducting bioassays, culturing test organisms, preparing and storing water, effluent, and sediment samples for use in the tests, routine chemical analyses, and TIE fractionations. The facility also has an additional 3,500 ft^2 of storage for supplies, laboratory equipment, and field equipment.

The laboratory facility is designed and organized to facilitate testing of environmental samples. The various laboratory rooms comprising our facility are all designed for efficient and optimal performance of the testing services we provide and include a total of nine large walk-in constant temperature rooms, five walk-in refrigerators, and eight water baths. A figure depicting the floor plan of the facility is provided as Figure 19-1.

Laboratory space is arranged to minimize cross-contamination between incompatible areas of the laboratory. For example, the organism culturing areas are separated from the testing areas and the sediment processing area is separated from the rest of the work areas. Some of the different laboratory work areas include:

- Sample receipt;
- Sample storage;
- Wet chemistry and analysis;
- Chemical storage;
- Toxicity testing;
- Organism culturing;
- Sediment sample processing;
- Special studies;
- Microscopic enumeration; and
- WER/TIE preparation.

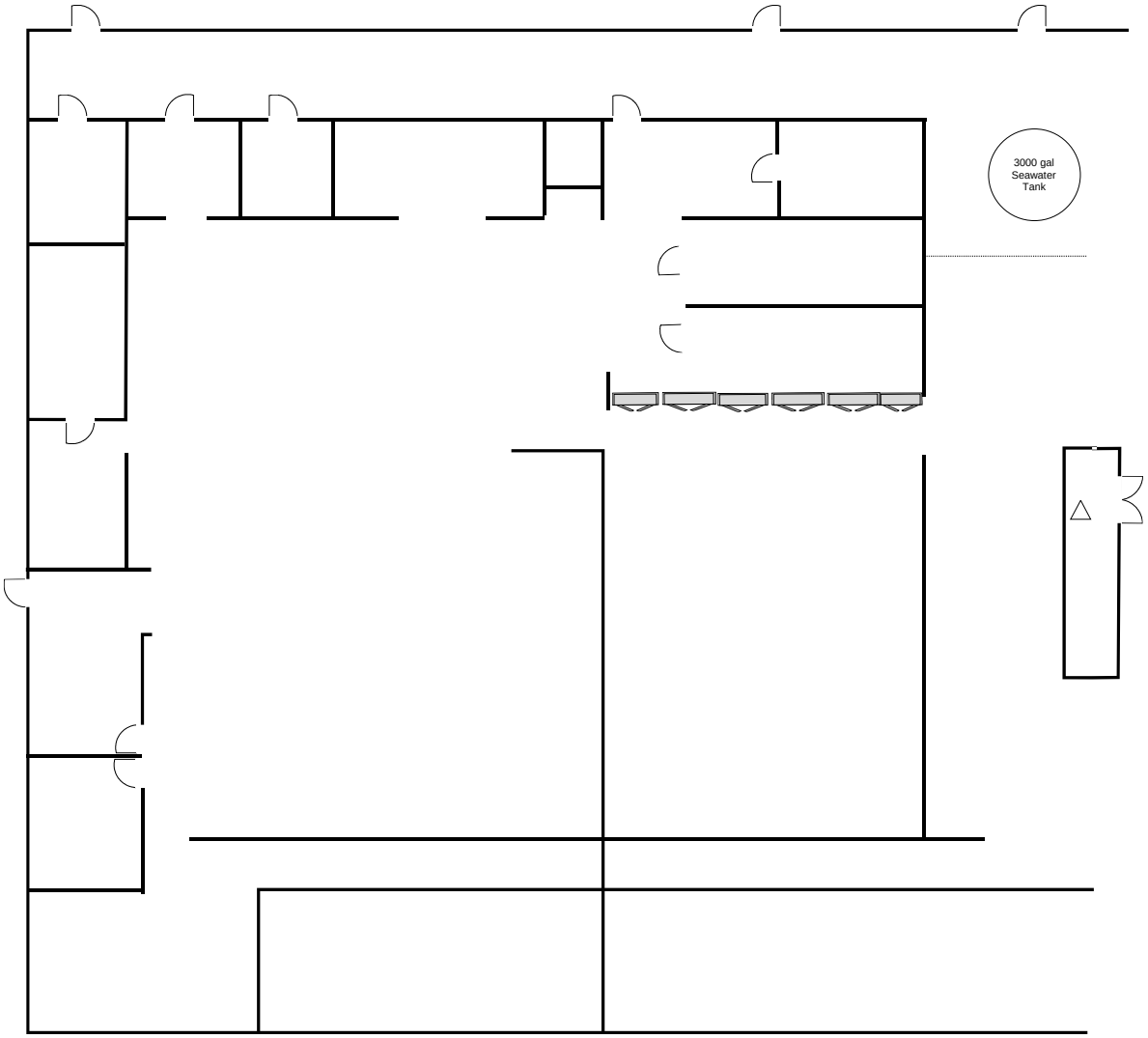
Environmental conditions (*e.g.*, temperature and light) are monitored to ensure that conditions do not invalidate results or adversely affect the required quality of any measurement.

The laboratory is kept secure during off hours with locks, an alarm system, and video surveillance. Laboratory personnel accompany all visitors in the facility.

PER provides accommodations for a variety of field activities and maintains a fleet of vehicles and sampling vessels to provide high quality sampling of creeks, rivers, agricultural drains,

lakes, ponds, bays, and estuaries. These vessels allow for sampling during inclement conditions and on limited notice. PER field staff are trained and approved for a variety of sampling procedures and use of sampling equipment including: surface water, stormwater, and sediment collection and monitoring, collection of field organisms, “Clean Technique” sampling, pesticide application monitoring, biological assessment, and physical habitat characterization.

Figure 19-1. Floor Plan



20. ENVIRONMENTAL METHODS AND METHOD VALIDATION

Methods and/or procedures are available for all activities associated with the analysis of samples, including preparation and testing. For purposes of this section, "method" refers to the toxicity test method. A table of the methods PER performs is attached in Appendix C.

Before being put into use, a method is confirmed by a demonstration of capability or method validation process. All methods are published or documented. Deviations from the methods are allowed only if the deviation is documented, technically justified, authorized by management, and accepted by the client.

20.1 Method Selection

PER will use methods that meet the needs of our clients. Such methods will be based on the latest edition of the method unless it does not meet the needs of the client. When the regulatory authority mandates or promulgates methods for a specific purpose, only those methods will be used. For example, toxicity testing for NPDES clients will be performed in accordance with their NPDES permit, using methods specified in 40 CFR Part 136.

If a method proposed by a client is considered to be inappropriate or out-of-date or if the method is not specified, the client is informed, and the issue is resolved before proceeding with analysis of any sample(s) (see Section 5). The client will be informed of the selected method and must approve its use before the method is used. All communications between the laboratory and the client are documented.

20.2 Laboratory-Developed Methods

For non-standard sampling and analysis methods, sample matrices, or other unusual situations, appropriate method validation study information shall be documented to confirm the performance of the method for the particular need. The purpose of this validation method is to assess the potential impact on the representativeness of the data generated. For example, if a non-standard method is used, rigorous validation of the method may be necessary. Such validation studies may include round-robin studies performed by USEPA or other organizations. If previous validation studies are not available, some level of single-user validation study should be performed during the project and included as part of the project's final report. The process of designing and validating the method is carefully planned and documented. All personnel involved in the method design, development, and implementation will be in constant communication during all stages of development. Approval of non-standard methods ultimately is the responsibility of the Technical Manager(s).

20.3 Method Validation

Validation is the confirmation, by examination and objective evidence, that the particular requirements for a specific intended use are fulfilled. At a minimum, all methods are validated by performing an initial demonstration of capability.

Non-standard methods may require additional validation documentation. The validation is designed so that the laboratory can demonstrate that the method is appropriate for its intended use. All records (*e.g.*, planning, method procedure, raw data, and data analysis) shall be retained while the method is in use. Based on the validation process, the laboratory will make a statement in the method or SOP of the intended use requirements and whether or not the validated method meets the use requirements.

20.4 Demonstration of Capability

Due to the following limitations, PER has established DOC documentation that separates the DOC documentation for staff analysts from the method itself:

- The duration of many toxicity tests occurs during a greater duration than the standard work week (*i.e.,* staff do not solely perform a toxicity test from test initiation to termination);
- The duration of toxicity tests (*i.e.,* one test can have a duration of more than 50 days for some methods) are too long for each analyst to demonstrate their capability by successful performance of five tests. The cost of training all staff analysts would be prohibitive due to the time requirements alone;
- The cost of test organisms makes ordering a separate batch of organisms for five tests for each test method for each analyst prohibitive; and
- The cost of test organisms and PT samples for five tests for each analyst for each test method for which PT samples can be obtained is cost prohibitive.

20.4.1 Demonstration of Capability for Scientist Staff

The Demonstration of Capability for staff is a procedure for analysts to become part of the work cell for a particular test method through demonstration of their ability to generate toxicity test results that meet the quality control requirements of the method. A summary of the analysts that have established their initial DOC and have maintained their ongoing DOC for each test method (or "work cell") is summarized on the "Scientific Demonstration of Capability Master List" that is posted in the laboratory. The process for analysts to develop their initial and ongoing DOC is established in Section 18.2.

20.4.2 Demonstration of Capability for Toxicity Testing Methods

A satisfactory initial Demonstration of Capability is required prior to acceptance and institution of any method for data reporting. It is also required to validate a non-standard method. DOC for a toxicity test method is a procedure to establish the ability of the work cell for a particular method to generate analytical results of acceptable accuracy and precision. Typically, this is achieved by performing a minimum of five acceptable reference toxicant tests, using the same test conditions, age of test organisms, feeding, etc., but different batches of test organisms are required for an initial DOC. The %CV for those five tests must be within the acceptable range specified in the test method in order to be considered a satisfactory initial DOC. The data is documented in the reference toxicant test database for that particular test method. When more than 20 tests have been performed, an ongoing DOC, consisting of no less than one annual test per test method, will satisfy this requirement. For method for which there are no reference toxicant test protocols (e.g., bioaccumulation testing), alternative approaches (e.g., laboratory control performance) may be used to establish a laboratory DOC. The documentation of ongoing laboratory performance (*i.e.*, ongoing DOC) is outlined in the corresponding toxicity test method manuals and includes documentation with Control charts. PER evaluates these regularly as part of the data review process (Section 23.4) and internal audits (Section 15.1).

20.5 Control of Data

To ensure that data are protected from inadvertent changes or unintentional destruction, the laboratory uses procedures to check calculations and data transfers (both manual and automated).

20.5.1 Computer and Electronic Data Requirements

PER ensures that computers, automated equipment, or microprocessors used for the acquisition, processing, recording, reporting, storage, or retrieval of environmental test data are:

- Documented in sufficient detail and validated as being adequate for use;
- Protected for integrity and confidentiality of data entry or collection, data storage, data transmission, and data processing;
- Maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of environmental test data; and
- Held secure, which includes the prevention of unauthorized access to and the unauthorized amendment of, computer records. Data archive security is addressed in Section 14 and building security is addressed in Section 19.

The laboratory controls access to all programs that are used to acquire, process, record, or report data. All programs are password-protected. Each employee is granted access only to those programs that he or she uses. The password is unique to the individual and cannot be shared. The company server is automatically backed up on a daily basis.

20.5.2 Data Reduction

As a part of the management system, PER ensures that another individual checks all manual calculations. In addition, all data transfers (data entry, transcribing raw or calculated data, etc.) are checked for accuracy. If any of the checked values are found to be incorrect, corrections are made to ensure that the calculations are correct. All raw data calculations are maintained in the appropriate project folder, or where appropriate (as described in Section 14).

20.5.3 Data Review Procedures

Data review procedures are located in Section 23.4.

20.6 Measurement Uncertainty

PER reports measurement uncertainty for quantitative analytical results under the conditions required by the TNI standard when required by the method, when instructed by a client, or when the uncertainty affects the compliance to a regulatory limit. PER uses a Type B method to evaluate measurement uncertainty. The Type B method uses historical data, experience with the behavior and properties of relevant materials and instruments, manufacturer's specifications, and data provided during calibration procedures (ISO 5725 Guide to the Expression of Uncertainty of Measurement).

21. LABORATORY EQUIPMENT

PER provides all the necessary equipment required for the performance of toxicity testing and field sampling. A list of the equipment used in the performance of the toxicity testing is provided in Appendix D. All equipment and software used for testing and sampling are capable of achieving the accuracy required for complying with the specifications of the environmental test methods as specified in the laboratory SOPs. Authorized and trained personnel operate equipment (see Section 18). All equipment is calibrated or verified before being placed in use to ensure that it meets laboratory specifications and relevant standard specifications.

Equipment and supply purchases are approved by a Technical Manager(s) and ordered by administrative staff (and designees). Supplies and equipment are ordered from a supplier on the "Approved Suppliers List". Following receipt of supplies and equipment, shipping manifests are given to administrative staff to ensure the correct items were received. Upon receipt, supplies and equipment are inspected and documented in the **Incoming Supplies and Equipment Approval Checklist** in order to ensure the supplies and equipment received comply with specifications prior to use in the laboratory.

The laboratory staff informs the administrative staff when consumable supplies or supplies with an expiration date (*e.g.*, chemicals and pH standards) need to be re-ordered in time to ensure that an adequate amount of supplies are available at all times.

21.1 Support Equipment Maintenance Program

PER considers all laboratory equipment to be support equipment. The Support Equipment Maintenance Program is overseen by the Quality Manager (and designees) and includes:

- A comprehensive list of laboratory support equipment;
- Support equipment maintenance and repair records;
- The specified frequency of maintenance tasks; and
- Support equipment maintenance and documentation task assignments.

The Support Equipment Maintenance Program includes but is not limited to: balances, ovens, refrigerators, freezers, incubators, water baths, temperature measuring devices, volumetric dispensing devices, pumps, fume hoods, microscopes, spectrophotometers, and a Type I water system. All equipment and instruments are maintained according to the requirements of the test method, the TNI Standard, and manufacturer recommendations. Regular maintenance of laboratory equipment is performed at least annually. Each piece of equipment is uniquely identified and all maintenance and repair information for each piece of equipment is recorded in an equipment maintenance log.

Equipment maintenance records include the following:

- Identity of the equipment and its software;
- Manufacturer's name, type identification, serial number, or another unique identifier;
- Check that the equipment complies with specifications of applicable tests;
- Current location;
- Manufacturer's instructions, if available, or a reference to their location;
- Dates, results, and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration (See Section 21.2);
- Maintenance plan, where appropriate, and maintenance carried out to date;
- Documentation on all routine and non-routine maintenance activities and reference material verifications; and
- Any damage, malfunction, modification, or repair to the equipment.

Equipment that is no longer used or maintained, has been subject to overloading or mishandling, given suspect results, or shown to be defective or outside specifications is taken out of service. The equipment is isolated to prevent its use or clearly labeled as being out of service until it has been shown to function properly. Before placing equipment back in service, maintenance and repair information is documented in the equipment maintenance log and the equipment must meet the requirements of the test method, the TNI Standard, and manufacturer recommendations. In and out of service dates are recorded for each piece of equipment.

If it is shown that previous tests are affected by equipment outside of specifications, then procedures for non-conforming work are followed and results are documented (see Section 10 and Section 12).

When equipment is used that is outside of permanent control of the laboratory, PER ensures the equipment meets the requirements of this manual prior to its use by inspecting or otherwise testing it.

All equipment and supplies purchased for laboratory use, including general supplies, must either be pre-cleaned or undergo laboratory cleaning before use in the toxicity tests.

21.2 Instrument Calibration and Standardization

Support equipment such as balances, ovens, refrigerators, and freezers are verified each day, prior to use, to ensure operation is within the expected range for the application for which the equipment is to be used. Verifications are performed with a NIST traceable reference or equipment calibrated with a NIST traceable reference. Volumetric dispensing devices (except Class A glassware and glass microliter syringes) are checked for accuracy in-house on a quarterly basis. Calibrations are performed annually by an external service provider.

All support equipment is calibrated or verified annually over the entire range of use using NIST traceable references, where available. The results of the calibration of support equipment meet method requirements or manufacturer specifications. If correction factors are used, this information is clearly marked on or near the equipment. Calibration of NIST traceable reference materials is outlined in Section 21.3.

Requirements for instrument calibration and standardization for use in toxicity tests and routine water quality analyses are briefly described below. Detailed descriptions of the analyses are described in laboratory SOPs. Each instrument calibration or verification is recorded in an instrument-specific logbook and are verified to be within method specifications prior to use each day.

Temperature - Temperature is measured to the nearest 0.1˚C using digital thermometers, alcohol thermometers, or continuous temperature measuring devices. All temperature measuring devices are verified semi-annually against a NIST traceable thermometer (See Section 21.3). Correction factors are assigned as needed. NIST traceable thermometers are re-calibrated every five years.

Conductivity/Salinity - Conductivity is measured to the nearest µS/cm and salinity is measured to the nearest 0.1 ppt or psu using a verified and calibrated meter. The meter and probe are used and maintained according to factory specifications. Standards are stored in accordance with the manufacturer's recommendations, method requirements, and the requirements of the Pacific EcoRisk Health and Safety Program. Handling of standards is minimized by using sub-samples for multiple calibrations. Calibrations are performed when verification values fall outside specifications.

pH - pH is measured to the nearest 0.01 pH unit using an appropriately-calibrated meter and probe. The meter and probe are used and maintained according to factory specifications. Each pH probe/meter is calibrated daily using buffer solutions that bracket the pH range of the samples (typically, pH buffers at pH 4, pH 7, and pH 10).

Dissolved Oxygen - Dissolved oxygen (DO) is measured to the nearest 0.1 mg/L with an appropriately calibrated meter and probe. The meter and probe are used and maintained according to factory specifications. Each probe/meter is calibrated as specified in the method or manufacturer's instructions.

Irradiance (Light) - Irradiance is measured using an appropriate meter and an irradiance sensor that measures photosynthetically active radiation (PAR, photons) in units of foot-candles or lux. Each meter is factory-calibrated at intervals recommended by the manufacturer.

Total Ammonia - Ammonia is measured to the nearest 0.01 mg/L using a spectrophotometer. The spectrophotometer is maintained according to factory specifications. Each water sample is added to a vial containing reagents and measured on the spectrophotometer using the factory-installed method for ammonia analysis.

Total Residual Chlorine - Chlorine is measured to the nearest 0.1 mg/L colorimetrically using an appropriate colorimeter. Each water sample is prepared for analysis using commercial reagents. The colorimeter is used and maintained according to factory specifications and is verified daily in accordance to manufacturer's instructions.

Weights and Volumes - Calibration of the balances is checked daily before use with weights traceable to NIST standards. Each balance is certified annually by a service representative and is used and maintained according to factory specifications. Calibration weights are calibrated annually by a service representative; weights are inspected and discarded if corroded or otherwise suspect. Liquid volumes contained or delivered by pipettes/pipettors are verified in-house on a quarterly basis by weighing volumes of distilled water on an analytical balance. Calibrations are performed annually by an external service provider.

21.3 Measurement Traceability

Measurement quality assurance comes in part from traceability of standards to certified materials. All equipment affecting the quality of test results are calibrated prior to being put into service and on a continuing basis (see Section 23). These calibrations are traceable to national standards of measurement where available. If traceability of measurements to SI units is not possible or not relevant, evidence for correlation of results through inter-laboratory comparisons, proficiency testing, or independent analysis is provided.

The laboratory handles and transports reference standards and materials in a manner that protects the integrity of the materials. Reference standard and material integrity is protected by separation from incompatible materials and/or minimizing exposure to degrading environments or materials. Reference standards and materials are stored according to manufacturer's recommendations and method SOP requirements and are stored separately from samples.

21.3.1 Reference Standards

The following reference standards are sent out for calibration to a national standard as indicated in Section 21.2:

- Class 1 weights; and
- NIST traceable reference thermometers.

The Class 1 weights are used for daily balance verification and are calibrated annually. The NIST traceable reference thermometer, used to calibrate all other thermometers and continuous temperature monitoring devices, is calibrated every five years.

21.3.2 Reference Materials

Reference materials are substances that have concentrations that are sufficiently well established to use for calibration or as a frame of reference. Reference materials, where commercially available, are traceable to national standards of measurement or to Certified Reference Materials, usually by a Certificate of Analysis.

Purchased reference materials require a Certificate of Analysis, where available. If a reference material cannot be purchased with a Certificate of Analysis, it is verified by analysis and comparison to a certified reference material and/or demonstration of capability for characterization.

Internal reference materials, such as reference toxicant stock solutions, working standards, or intermediate stock solutions, are checked as far as is technically and economically practical and are documented as outlined in Section 21.4.

21.4 Standards, Reagents, and Reference Materials

The laboratory has procedures for purchase, receipt, distribution, and storage of standards, reagents, and reference materials as described in Section 7 and the Pacific EcoRisk Health and Safety Program.

Expiration dates can be extended if the reference standard or material's integrity is verified. The extended date may not be beyond the expiration date of the referenced standards used to re-verify.

All containers of prepared standards, reagents, or materials are labeled with the material (*e.g.*, KCl), date prepared, and concentration (*i.e.*, this information constitutes our unique ID).

Prepared reagents are verified to meet the requirements of the test method through traceability to purchased stock or neat chemicals. Purchased reagent quality is verified to meet the requirements of the test method upon receipt following procedures in the **Incoming Supplies and Equipment Approval Checklist**. If the original container does not have an expiration date provided by the manufacturer or vendor, it should be labeled with an expiration date that is three years after the receipt date. If an expiration date is provided, the original containers and container of any standards or reagents prepared from it must be labeled with the expiration date.

21.4.1 Purchased Standards, Reagents, Reference Materials, and Media

Records for all standards, reagents, reference materials, and media are recorded in the chemical inventory and include the:

- Manufacturer/vendor name (or traceability to purchased stocks or neat compounds);
- Manufacturer's Certificate of Analysis or purity (if supplied);
- Date of receipt; and
- SDS.

In methods where the purity of reagents is not specified, reagent grade is used. If the purity is specified, that is the minimum acceptable grade. Purity is verified and documented according to Section 7.

21.4.2 Prepared Standards, Reagents, Reference Materials, and Media

Records for preparation of standards, reagents, reference materials, and media should include:

- Traceability to purchased stock or neat compounds;
- Reference to the method of preparation;
- Date of preparation;
- Expiration date after which the material shall not be used (unless its reliability is verified by the laboratory); and
- Preparer's initials.

22. SAMPLE COLLECTION AND HANDLING

PER provides sampling services on a project specific basis. For these projects, sampling SOPs can be found in the corresponding QAPP or SAP. The laboratory uses sampling plans provided by clients or prepared in consultation with the client. The plan must include any factors that must be controlled to ensure the validity of the test. Sampling plans and written sampling procedures are used for collecting environmental samples, substances, materials, or products for testing. The QAPP or SAP is made available at the sampling location. When the client requests any deviations from the sampling plan or sampling procedures, the deviations are documented and

included in the final report. All field measurements, records, and notes (*e.g.*, temperature, salinity, etc.) are logged in bound field notebooks when samples are collected by PER staff. Sufficient information is recorded in detail in the field notebook to completely reconstruct the sampling event(s).

Precautions are taken to ensure that methods for collection and storage of samples (including materials used) do not contribute to sample toxicity (*i.e.*, use appropriately cleaned sample containers, etc.); this may include the use of field blanks, which will be specified in the project QAPP. Samples may be shipped in glass or plastic (*e.g.*, polyethylene or polypropylene) bottles, or in disposable cubitainers. All samples should be shipped on ice, under chain-of-custody with a temperature blank.

For projects for which PER does not provide sampling services, the laboratory provides the sampler with the necessary coolers, sample containers, COC forms, and packing materials required to properly preserve, pack, and ship samples to the laboratory.

22.1 Sampling Containers

The laboratory offers clean sampling containers for use by clients. Containers are obtained following procedures outlined in Section 7 and meet the requirements of the test methods. Containers are provided to the client upon request.

22.2 Chain-of-Custody

The purpose of using a chain-of-custody (COC) record is to maintain an accurate written record that can be used to trace the custodianship of the sample from its collection through its receipt at the PER testing laboratory. COC documentation begins in the field. The sample collector is responsible for the care and custody of the sample(s) until they are received at the appropriate laboratory or relinquished to an assigned custodian.

Samples must be accompanied by a COC record that includes the name of the study, a unique sample ID for each sample, location of collection (or station number and location), date and time of collection, type of sample, number of containers, analysis required (including applicable method number), and the collectors' signatures. The COC can act as an order for laboratory services in the absence of a formal contract. When turning over possession of samples, the person relinquishing the sample(s) *and* the recipient must *both* record the date and time of the transfer and sign their name to verify the transaction. For certain projects, an additional sample transfer sheet is initiated to track the sample through the laboratory during storage, sample preparation, and generation of raw data. Samples are discarded only upon approval of a Technical Manager(s) after it is certain that all tests and analyses have been properly performed and recorded. An example COC is provided in Appendix E. Chain-of-custody and any additional

records received at the time of sample submission are maintained by the laboratory in the project folder and is provided in the final report.

22.3 Sample Receipt, Handling, Storage, and Disposal

Upon receipt, staff ensure each sample has an identification label or tag securely attached to the sample container. If PER is collecting the samples, staff ensure the sample is labeled at the time of collection. The sample label, including any subsamples for auxiliary analyses, typically contains the following information:

- Name of the client and project;
- Sampling station name/location;
- Sample date, time, and duration, where applicable, of sample collection;
- Type of sample (*i.e.*, grab vs. composite); and
- Unique identifying number.

Samples are delivered to the laboratory via third-party shipper, courier (either PER staff or contracted), or the client. Procedures for picking up samples by PER staff are outlined in the **Sample Pickup SOP**. Samples that are transported under the responsibility of PER, where necessary, are done so safely and according to storage conditions. This includes moving bottles within the laboratory. Sample shipping procedures are described in the **Sample Shipment SOP**.

The laboratory has sample acceptance, storage, and disposal procedures that are provided in the **Sample Receipt & Handling SOP** and the **Sample and Test Solution Disposal SOP**. Upon receipt at the laboratory, all samples are assessed to determine if the sample was compromised. If so, the Project Manager is informed and contacts the client to determine whether or not the sample will be used for testing. If to be used in testing, all samples are assigned a unique sample ID number. This number is used throughout the project. For effluent and receiving/ambient water samples, measurement of initial temperature, pH, D.O., salinity, conductivity, and total ammonia, as well as the initials of the person that recorded the data, are recorded on the sample login sheets. Total residual chlorine is also measured for effluents collected from facilities that use chlorination in their disinfection process. The remaining sample is stored at 0-6˚C until completion of all testing and analysis. A Project Manager must provide approval for sample disposal, at which time the sample is removed from storage and any client identification is obliterated by blacking out the label prior to disposal. PER maintains SOPs for all required analyses that are available to staff.

PER complies with the sample hold time requirements found in the applicable toxicity testing SOP(s). If preservation or holding time requirements outlined in the SOP or test methods are not met, deviations shall be documented on the sample log-in data sheet. In general, if these conditions are not met, the client is contacted by the Project Manager prior to any further processing. The sample is then either rejected or the decision to proceed is documented and

agreed upon with the client. The condition is noted on the sample log-in sheet and the data are qualified in the report.

23. QUALITY ASSURANCE FOR ENVIRONMENTAL TESTING

PER has procedures for monitoring the validity of the testing it performs. To evaluate the quality of toxicity test results, the laboratory utilizes standard toxicity testing QA/QC procedures to ensure that the test results are valid. Standard QA/QC procedures include the use of negative controls, positive controls (reference toxicant tests), reference sediment samples, replicates, and measurements of water quality during testing.

Toxicity testing results are analyzed and, when found to be outside pre-defined criteria, action is taken to correct the problem and to prevent incorrect results from being reported. Data associated with quality control data outside of criteria and still deemed reportable will be qualified so the end user of the data may decide regarding the usability of the data. The corrective actions taken are dependent upon the magnitude of the problem.

23.1 Essential Quality Control Procedures

Laboratory personnel follow the quality control procedures specified in test methods and Data Quality Objectives (DQOs) identified in project specific QAPPs. For test methods that do not provide acceptance criteria for an essential quality control element or where no regulatory criteria exist, acceptance criteria would be developed based on information in the literature or best professional judgment.

Written procedures to monitor routine quality controls, including acceptance criteria, are located in the test method SOPs and include such procedures as:

23.1.1 Source and Condition of Organism

All test organisms are obtained from reputable suppliers who have provided PER with organisms in the past. Normally, all test organisms are maintained in the laboratory for acclimation to test conditions. If mortality in excess of 10% is noted during holding, the Project Manager is informed and may decide that the animals be discarded, and a new batch ordered. If mortality in excess of 10% is noted in the culture 24-hours prior to test initiation and the animals are to be used per Project Manager instruction, a deviation form is attached to the associated testing. All organism suppliers must provide taxonomic identification documentation annually.

23.1.2 Maintenance of Test Conditions and Corrective Actions

Each of the biological tests has a set of specific test conditions that are defined in the standard testing. For example, water quality measurements are monitored to ensure that test conditions are

within the prescribed limits for each test procedure. The limits for various test condition parameters are noted in the section on the acceptability of each test.

23.1.3 Reference Toxicant Testing and Data Accuracy and Precision

Reference toxicant tests are used to assess accuracy (*i.e.*, to establish that the test organisms are responding to toxic stress in a typical fashion). For instance, acceptable accuracy is defined as a calculated reference toxicant dose-response value (*i.e.*, statistically-derived point estimate such as the EC_{50} or IC_{25}) that is within the "typical test organism response" range established by the mean ± 2 standard deviations of the 20 most-recently performed tests; this information is maintained in the PER reference toxicant database and can be quickly assessed by reviewing the reference toxicant control charts. Reference toxicant testing performance is determined by reviewing the data against the EPA method requirements.

PER performs toxicity testing with species for which a minimum of 5 reference toxicant tests have been completed with different batches of organisms. If a specific project requires the performance of a reference toxicant test, the reference toxicant testing may be performed concurrently or monthly; this is determined by the client's permit. A monthly reference toxicant test must be performed for any species tested for a project in a month's time, even if the project did not require the performance of a reference toxicant test. In addition, a reference toxicant test is performed for each species at least on an annual basis.

The precision of toxicity tests is assessed via measures of variability (*e.g.*, coefficient of variation [CV] for a given test treatment). While there are no "acceptability limits" placed on the CV for most test responses, these can be evaluated using "best professional judgment" to characterize whether or not the test response at a given treatment is subject to too much variability for use in a given test.

23.2 Internal Quality Control Practices

The following procedures are performed as internal quality control checks to ensure that all infrastructural functions and generation of data in the laboratory are within acceptable performance ranges:

- Test temperature monitoring;
- Type I water quality monitoring;
- Review of test data;
- Instrumentation calibration log entries and reviews;
- Test organisms' log-in and husbandry log;
- Sample log-in;
- Calibration of equipment according to SOPs;
- Continual training of laboratory personnel, including their ethical and legal responsibilities; and

- All QC data is assessed and evaluated on an on-going basis, so that trends are detected.

23.3 Proficiency Test Samples or Inter-Laboratory Comparisons

PER participates in applicable proficiency testing (PT) or inter-laboratory comparisons (*e.g.*, DMR-QA). The proficiency standard testing program consists of a yearly toxicant test regulated by external agencies. Toxicity testing is performed on all available and applicable PT samples. PT results are made available and clients are notified of results and any related corrective actions.

The laboratory does not share PT samples, communicate results, or attempt to obtain the assigned values or results from other laboratories or PT providers. PT samples are treated as standard testing samples and processed using standard procedures.

23.4 Data Review

Throughout testing, as well as upon completion of a project, a thorough data review is performed. The data review consists of the following procedures:

- Determinations of whether the results of testing, examining, or analyzing the sample meet the accepted protocols for interpretation;
- Checks to determine the accuracy of any calculations;
- Checks for transcription errors, omissions, or mistakes;
- Checks to determine consistency with project-specific measurement quality objectives;
- Checks to ensure that the appropriate preparatory and analytical SOPs and standardized methods were followed;
- Checks to ensure that the chain-of-custody is complete and that holding times were met;
- Checks to ensure that requirements for equipment calibrations were met; and
- A tiered system of verification/review consisting of the Scientist performing the testing, Laboratory Manager (or designees) verifying performance, Quality Manager (or designees) reviewing results, and a Project Manager/Technical Manager(s) reviewing reports.

24. REPORTING RESULTS

The results of each test performed are reported accurately, clearly, unambiguously, and objectively and comply with all specific instructions contained in the test method.

Laboratory results are reported in a test report that includes all the information requested by the client and necessary for the interpretation of the test results and all information required by the method used.

24.1 Test Reports

The report format has been designed to accommodate each type of test performed and to minimize the potential for misunderstanding or misuse. Each test report generated contains the following information:

- Title;
- Name and address of the laboratory;
- Unique project identification number for the test report and a pagination system that ensures that each page is recognized as part of the test report and a clear identification of the end of the report, such as *3/10*;
- Name and address of the client;
- Identification of the method used;
- Description of, the condition of, and unambiguous identification of the sample(s) tested, including the client identification code;
- Date of sample receipt when it is critical to the validity and application of the results, date and time of sample collection, dates the tests were performed, the time of sample preparation and analysis, if the required holding time for either activity is less than or equal to 72 hours;
- Reference to the sampling plan and procedures used by the laboratory where these are relevant to the validity or application of the results;
- Test results, an indication of when non-conforming data is identified, and an identification of the statistical package used to analyze the data;
- Name, function, signature (or equivalent electronic identification) of the person authorizing the test report, and the date of issue;
- Where relevant, a statement to the effect that the results relate only to the samples;
- Any non-accredited tests or parameters are clearly identified as such to the client; and
- Statement that the report shall not be reproduced except in full without written approval of the laboratory.

24.2 Supplemental Test Report Information

When necessary for interpretation of the results or when requested by the client, test reports include the following additional information:

- Deviations from, additions to, or exclusions from the test method, information on specific test conditions (*e.g.*, environmental conditions), any non-standard conditions that may have affected the quality of the results, and any information on the use and definitions of data qualifiers;

- Statement of compliance/non-compliance when requirements of the management system are not met including identification of test results that did not meet the laboratory and regulatory sample acceptance requirements (*e.g.*, holding time);
- Where applicable and when requested by the client, a statement on the estimated uncertainty of the measurement;
- Where appropriate and needed, opinions and interpretations. When opinions and interpretations are included, the basis upon which the opinions and interpretations are constructed are documented. Opinions and interpretations are clearly marked as such in the test report; and
- Additional information that may be required by specific methods or client.

In addition to the items above, the following is provided when necessary for the interpretation of the results for test reports that contain the results of sampling:

- Date of sampling;
- Unambiguous identification of the material sampled;
- Locations of the sampling, including diagrams, sketches, or photographs;
- Reference to the sampling plan and procedures used;
- Details of any environmental conditions during sampling that may affect the interpretations of the test results; and
- Any standard or other specification for the sampling method or procedure and deviations, additions to, or exclusions from the specification concerned.

24.3 Environmental Testing Obtained from Subcontractors

Test results obtained from tests performed by subcontractors are clearly identified on the test report by subcontractor name and/or accreditation number. The subcontractors report their results in writing or electronically. A copy of the subcontractor's report is provided as an appendix to the client's report.

24.4 Electronic Transmission of Results

All test results transmitted by telephone, fax, telex, e-mail, or other electronic means comply with the requirements of the TNI Standard and associated procedures to protect the confidentiality and proprietary rights of the client. PER controls electronic documents with Adobe Acrobat® electronic signatures to prevent unauthorized modification to test reports.

24.4.1 Electronic Data Deliverables

Electronic data deliverables (EDD) include PDF copies of toxicity reports and Surface Water Ambient Monitoring Program (SWAMP) EDDs. The SWAMP EDDs are generated via a cross walk from the CETIS statistical software and are then populated with additional information (*e.g.*, pH, dissolved oxygen, conductivity, etc.) that are not included in the CETIS entry. Scientist

III or Project Managers review all SWAMP EDDs and ensure that they conform to the SWAMP data entry requirements.

24.5 Amendments to Test Reports

Material amendments to a test report after it has been issued are made only in the form of a "supplemental" report with the revisions being clearly identified in the report cover letter. An electronic version of each supplemental report is saved with a suffix that includes the letter "S" for supplemental and a number (*e.g.*, "1") for the number of the supplement so as to clearly distinguish it from the initial version of the report. All supplemental reports meet all the requirements for the initial report and the requirements of this Quality Manual.

Appendix A

Laboratory Accreditation/Certification/Recognition

Pacific EcoRisk maintains the following certifications and accreditations with state and national entities:

Organization	Certification	Certificate Number
Oregon Health Authority	NELAP	4043
California Department of Public Health	ELAP	2085
Washington Department of Ecology	ELAP	C848

The certificates and parameter lists (which may differ) for each organization are provided on the Fields of Accreditation included with the accreditation certificate, which are stored in the QA/QC Program folder on the Pacific EcoRisk server.

Should accreditation be terminated or suspended, Pacific EcoRisk would immediately cease to use the certificate number reference in any way and inform clients impacted by the change.

Appendix B

Glossary

Glossary

Accuracy	Degree of agreement between an analytical result and the true value. Accuracy is affected by both random error (imprecision) and systematic error (bias) but is sometimes used improperly to denote only systematic error.
Analytical Method	Written instructions describing an analytical procedure followed to obtain a numerical estimate of the chemical (analyte) in a sample or samples.
Blank	A sample expected to contain none of the analyte or chemical of interest. *Field blanks* are used to obtain information on contamination introduced during sample collection, transport, or storage. *Method blanks* are most commonly used to reveal contamination in the laboratory (as opposed to in the sampling process) or as an assessment of the effects of a given treatment in a TIE study.
Control Chart	A graphical representation of the precision of QC test results indicating whether the measurement system is in statistical control. For repeated analyses of standards, the chart is usually based on the average result of those analyses (20 results are generally accepted as the minimum to ensure valid statistics) and upper and lower control limits based on the standard deviation of the results. (See *Control Limits*)
Control Limits	Statistical warning and action limits calculated for control charts, used to make decisions on acceptability of control test results. *Warning limits* usually established at two standard deviations above and below the mean of repeated analyses of a standard. *Action limits* are established at three standard deviations.
Holding Time	The allowed time from when a sample was collected or extracted until it must be analyzed. For composite samples, the holding time starts when the last composite aliquot is collected.
Precision	A measure of the variability (spread) in the results for replicate measurements caused by random error. Also referred to as *imprecision*. Precision is usually measured as *standard deviation, percent relative standard deviation* (%RSD), or *relative percent difference* (RPD).
Quality Assurance	The total integrated program for ensuring the reliability of monitoring and measurement data.
Quality Control	The routine application of statistically based procedures to evaluate and control the accuracy of results from analytical measurements.
Standard Operating Procedure	A detailed written description of a procedure designed to systematize performance of the procedure.

Appendix C

Toxicity Test Methods

Methods Used for Aquatic Effluent & Receiving Water Toxicity Testing
Ambient Water Quality/Toxicity Monitoring

Certification	Manual	Title	Method	Species
NELAP ELAP	EPA-821-R-02-012	Methods for measuring the acute toxicity of effluents to freshwater and marine organisms, Fifth Edition	2002.0 2021.0 2019.0 2000.0 2007.0 Topsmelt 2004.0 2006.0 *Hyalella* *Chironomus*	*Ceriodaphnia dubia* *D. magna* *D. pulex* *Oncorhynchus mykiss* *Pimephales promelas* *Americamysis bahia* *Atherinops affinis* *Cyprinodon variegatus* *Menidia beryllina* *Hyalella azteca* *Chironomus dilutus*
NELAP ELAP	EPA-821-R-02-013	Short-term methods for estimating the chronic toxicity of effluents and receiving waters to freshwater organisms, Fourth Edition	1003.0 1002.0 1000.0	*Selenastrum capricornutum* *Ceriodaphnia dubia* *Pimephales promelas*
NELAP ELAP	EPA-821-R-02-014	Short-term methods for estimating the chronic toxicity of effluents and receiving waters to marine and estuarine organisms, Third Edition	1007.0 1006.0 1004.0 1006.0	*Americamysis bahia* *Cyprinodon variegatus* *Menidia beryllina*
NELAP ELAP	EPA/600/R-95-136	Short-term methods for estimating the chronic toxicity of effluents and receiving waters to West Coast marine and estuarine organisms	1005.0 1008.0 Sand Dollar 1008.0 Purple Urchin 1005.0 1009.0 Red Abalone	*Crassostrea gigas* *Dendraster excentricus* *Strongylocentrotus purpuratus* *Mytilus spp.* *Macrocystis pyrifera* *Haliotis rufescens* *Atherinops affinis*
NELAP ELAP	ASTM-1218	Standard guide for conducting static toxicity tests with of microalgae	E-1218	*Selenastrum capricornutum* *Thalassiosira pseudonana* *Skeletonema costatum*
NELAP ELAP	Polisini & Miller	Static acute bioassay procedures for hazardous waste samples	Polisini & Miller	*Pimephales promelas* *Oncorhynchus mykiss*

Methods Used for Sediment Toxicity & Bioaccumulation Testing Evaluations of Ambient Sediments, Dredged Materials, and Dredging Operations

Certification	Manual	Title	Method	Species
NELAP	EPA 600/R-99/064	Methods for measuring the toxicity and bioaccumulation of sediment-associated contaminants with freshwater invertebrates, Second Edition	100.1 100.2 100.3 100.4 100.5	*Hyalella azteca* *Chironomus dilutus* *Lumbriculus variegatus*
NELAP	EPA 600/R-94/025	Methods assessing the toxicity of sediment-associated contaminants with estuarine and marine amphipods	100.4	*Ampelisca abdita* *Eohaustorius estuaries* *Leptocheirus plumulosus* *Rhepoxynius abronius*
N/A	EPA/600/R-01/020	Methods assessing the chronic toxicity of marine and estuarine sediment-associated contaminants with the amphipod *Leptocheirus plumolosus*	N/A	*Leptocheirus plumulosus*
N/A	ASTM E724	Standard guide for conducting toxicity tests starting with embryos of four species of saltwater bivalve molluscs	E724	*Crassostrea gigas* *Mytilus spp.*
NELAP	ASTM E1676-12	Standard guide for conducting laboratory soil toxicity or bioaccumulation tests with the lumbricid earthworm *E. fetida* and the enchytraeid potworm *E. albidus*	E1676-12	*Eisenia fetida*
N/A	ASTM E1367	Standard test method for measuring the toxicity of sediment-associated contaminants with estuarine and marine invertebrates	E1367	*Ampelisca abdita* *Eohaustorius estuaries* *Leptocheirus plumulosus* *Rhepoxynius abronius*
NELAP	ASTM E1611	Standard guide for conducting sediment toxicity test with polychaetous annelids	E1611	*Neanthes arenaceodentata*
NELAP	ASTM E1688	Standard guide for determination of sediment-associated contaminants by benthic invertebrates	E1688	*Macoma nasuta* *Nereis virens* *Nephtys caecoides*
N/A	ASTM E1706	Standard test method for measuring the toxicity of sediment-associated contaminants with freshwater invertebrates	E1706	*Hyalella azteca* *Chironomus dilutus*

Toxicity Identification Evaluations / Toxicity Reduction Evaluations (TIEs / TREs)

- Methods for Aquatic Toxicity Identification Evaluations: Phase 1 Toxicity Characterization Procedures (Second Edition). EPA-600/6-91/003. U.S. EPA, Environmental Research Laboratory, Duluth, MN.
- Methods for Aquatic Toxicity Identification Evaluations: Phase II Toxicity Identification Procedures for Samples Exhibiting Acute and Chronic Toxicity. EPA/600/R-92/080. U.S. EPA, Office of Research and Development, Washington, D.C.
- Methods for Aquatic Toxicity Identification Evaluations: Phase III Toxicity Confirmation Procedures for Samples Exhibiting Acute and Chronic Toxicity. EPA/600/R-92/081. U.S. EPA, Office of Research and Development, Washington, D.C.
- Toxicity Reduction Evaluation Protocol for Municipal Wastewater Treatment Plants. EPA/600/2-88/062. U.S. EPA, Water Engineering Research Laboratory, Cincinnati, OH.
- Sediment Toxicity Identification Evaluation (TIE): Phase 1, Phase II, and Phase III Guidance Document. EPA-600/R-07/080. U.S. EPA, Office of Research and Development, Washington, D.C.

References

- Long-term management strategy (LTMS) for the placement of dredged material in the San Francisco Bay Region. U.S. EPA Region 9, U.S. Army Corps of Engineers, San Francisco Bay Conservation and Development Commission, San Francisco Bay Regional Water Quality Control Board, California State Water Resources Control Board.
- Evaluation of dredge material proposed for ocean disposal - Testing Manual. EPA-503/8-91/001. U.S. EPA-U.S. Army Corps of Engineers, Washington, D.C.
- Evaluation of dredged material proposed for discharge in waters of the U.S. - Inland Testing Manual. EPA-823/B-94/002. U.S. EPA-U.S. Army Corps of Engineers, Washington, D.C.
- QA/QC guidance for sampling and analysis of sediments, water, and tissues for dredged material evaluations. Phase 1 - Chemical evaluations. EPA 823-B-95-001. U.S. EPA, Office of Water, Washington, D.C.
- Guidance manual: bedded sediment bioaccumulation tests. EPA-600/X-89/302. U.S. EPA Environmental Research Laboratory, Newport, OR.
- Standard test method for measuring the toxicity of sediment-associated contaminants with freshwater invertebrates. ASTM E1706. American Society for Testing and Materials, Philadelphia, PA.
- Standard guide for collection, storage, characterization, and manipulation of sediments for toxicological testing and for selection of samplers used to collect benthic invertebrates. ASTM E1391-03. American Society Testing & Materials, Philadelphia, PA.
- Sediment toxicity identification evaluation: Phase 1 (characterization), Phase II (identification), and Phase III (confirmation). Modifications of effluent procedures. EPA-600/6-91/007. U.S. EPA, Environmental research Laboratory, Duluth, MN.

Appendix D

Laboratory Equipment

Laboratory Equipment

Laboratory Equipment - Pacific EcoRisk has all of the equipment necessary to successfully perform the EPA and ASTM water, effluent, soil, and sediment toxicity tests. All testing and analytical equipment is maintained and calibrated as per the Quality Manual. All plastic and glass labware is cleaned according to EPA guidelines and is stored in clean, dust-free cabinets until used. A selected list of PER laboratory testing equipment is provided on the accompanying pages.

Toxicity Testing

Market Forge Ind.	STERILMATIC	Electric Autoclave
VWR	S-500	Platform Shaker
Porta-Trace	1118-30W	Light Boxes
Stanplatec	Drykeeper	Desiccators
Air Whist	AW-1000	Air Pumps
Sweetwater	Blower S-31	Regenerative Blower
Rio	2100	Circulation Pumps
Universal Marine Ind.	UTCH-2	Digital Chiller/Heater Units
EBO-Jäger	250W	Submersible Heaters
VWR	2005	Low Temperature Incubator
Westpointe/Lakewood/ Honeywell/Holmes/Vornado	Multiple	Electrical Fans
Intermatic	TN311	Light Timers
BOHN/Heat Craft/Keepright	Multiple	Temperature-Controlled Rooms

Microscopy

Leica	DM500	Compound Microscope
Wolfe	N/A	Dissecting Microscope
Leica	Stereozoom 5	Dissecting Microscope
Zeiss	Invertoskop	Inverted Microscope
Leica	DFC290	Microscope Camera
Leica	DMIL	Inverted Microscope
Hausser Sci.	3800	Sedgewick-Rafter Chamber
Reichert	N/A	Hemocytometers

Balances and Weights

Ohaus	AP2500	Analytical Balance
Mettler/Toledo	MS40025	Top Loading Balance
Ohaus	Scout II Top Loader	Top Loading Balance
Ohaus	DU215CD	Discovery Balance
Ohaus	D71P60HR1	Top Loading Balance
VWR	VWR-450TC	A-Series Balance
VWR	Class S	Calibration Weights

Water Quality Analyses

Orion	3-Star	D.O. Meter
Orion	5-Star	Conductivity/Salinity meter
Orion	Star A221	pH meter
Beckman	pH 1410	pH meter
Beckman	pH 410	pH meter
Control Company	35519-055	Barometer
CO_2 Meter.com	0-30% CO_2 Sampler	CO_2 meter
Hach	DR/3900	Spectrophotometer
Hach	DR/3800	Spectrophotometer
Hach	Pocket II	Colorimeter
VWR	Dual-Range	Illuminance Meter
Onset	UTBI-001	Continuous Temperature Loggers
Hach	N/A	Digital Titrators
VWR	Multiple	Digital Thermometers
H-B Instrument Co.	NIST	NIST Thermometer

Sample Storage

Raetone	AR-47-SS	Laboratory Refrigerator
LG	LBC225	Industrial Refrigerator
True	H-74	Industrial Refrigerator
Frigidaire	FFU21M7HWJ	Industrial Freezer
Hochizaki	KM-230BAL	Ice Machine
Heat Craft/Keepright	Multiple	Cold Storage Rooms

Sample Manipulation/Preparation

Forma Scientific	5682	Centrifuge
Forma Scientific	Centra-GP8R	Centrifuge
Beckman Coulter	Avanti J-15R	Centrifuge
Hydro-Photon Inc.	Steripen Classic	Handheld UV Light
Laguana Clay Co.	N/A	Sediment Termination Booths
IKA	IKA-RW20-DS1	Benchtop Elutriate Mixer
Bellco	N/A	Roller Apparatus
Nalgene	N/A	Filtration Units
ASTM	Various mesh	ASTM Stainless Steel Sediment Sieves
Corning/VWR	Multiple	Magnetic Stirplates

Laboratory Water Storage/Preparation

Pentair	PS53SS	Seawater Pump
Little Giant	TE-5.5-MD-HC	Seawater Pump
Ryan Herco	3000 Gallon	Seawater Tank
Pacific Water Systems	Type I Water	RO/DI System
Lifeguard Aquatics	Aquastep 25W	UV Sterilizer
Emperor Aquatics	Smart UV 25W	UV Sterilizer
Cora Lite	Turbo Twist 36W	UV Sterilizer
Pentair	Smart Lite	UV Sterilizer

Pondmaster	24, 700, and 1200	Magnetic Drive Pumps
Danner	Model 7	Magnetic Drive Pumps

General Laboratory Equipment

Scienceware	N/A	Calipers
VWR Scientific	1326	Gravity Oven
Thermolyne	N/A	Benchtop Muffle Furnace
MasterFlex	L/S and H/S	Peristaltic Pumps
Gast	DAA-V715-EB	Vacuum Pump
Miele Professional	G 7804	Lab Glassware Dishwasher
Gilson/Rainin/Eppendorf/ Nichiryo/Accupet	N/A	Automatic Pipettors
Pyrex	Class A	Volumetric Pipettes/Flasks
Pyrex/Nalgene	Misc. Griffin beakers	
Pyrex/Nalgene	Misc. Erlenmeyer Flasks	
Pyrex/Nalgene	Misc. Graduated Cylinders	

Safety Equipment

Bradley	Barrier Free	Eyewash Station
Bradley	519-270HD	Eyewash Station
Kiddie	Pro 340	Fire Extinguishers
Labconco	1060200	Fume/Ventilation Hood
Labconco	N/A	Acid Storage Cabinet
Labconco	N/A	Solvent Storage Cabinet
Global	N/A	Safety Storage Cabinet
Hydro Farm	ACDF8	Air Scrubber
Champion	100161	Portable Generator

Appendix E

Chain-of-Custody Form

Pacific EcoRisk
2250 Cordelia Rd., Fairfield, CA 94534
(707) 207-7760 FAX (707) 207-7916

CHAIN-OF-CUSTODY RECORD

Results To:				**Invoice To:**																
Address:				**Address:**																
Phone:				**Phone:**																
Attn:				**Attn:**																
E-mail:				**E-mail:**																
Project Name:																				
P.O.#/Ref:																				

REQUESTED ANALYSIS

	Client Sample ID	**Sample Date**	**Sample Time**	**Sample Matrix***	**Grab/ Comp**	**Container Number**	**Container Type**
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							

Samples Collected By:

Comments/Special Instruction:

RELINQUISHED BY:	**RECEIVED BY:**
Signature:	**Signature:**
Print:	**Print:**
Organization:	**Organization:**
Date: **Time:**	**Date:** **Time:**
RELINQUISHED BY:	**RECEIVED BY:**
Signature:	**Signature:**
Print:	**Print:**
Organization:	**Organization:**
Date: **Time:**	**Date:** **Time:**

***Example Matrix Codes**: (**EFF** - Effluent) (**FW** = Freshwater); (**SW** = Saltwater); (**WW** = Wastewater); (**STRMW** = Stormwater); (**SED** = Sediment); or other